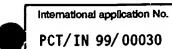
PATENT COOPERATION TREATY
PCT

# INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| Applicant's or agent's file reference  IN/PA-98  | FOR FURTHER ACTION   | see Notification (Form PCT/ISA/2 | of Transmittal of Int<br>220) as well as, wh | ternational Search Report<br>ere applicable, item 5 below. |  |
|--|--|----------------------------------|--|--|--|
| International application No.  | International filing date (da  | v/month/war)                     | T /Fortings/ Date of                         |  |  |
| PCT/IN 99/00030  |  | ,                                | (Eartiest) Phon                              | y Date (day/month/year)                                    |  |
| Applicant  | 15/07/19   | <del>9</del> 9                   |  |  |  |
| KHANNA, Pushpa   |  |                                  |  |  |  |
| This international Search Report has been according to Article 18. A copy is being tra   | The second of th | ર્યો Searching Auth<br>Bureau.   | ority and is transm                          | litted to the applicant                                    |  |
| This international Search Report consists  | of a total of5   | sheets.                          |  |  |  |
| it is also accompanied by  | a copy of each prior art docur   | nent cited in this               | report.                                      |  |  |
| 1. Basis of the report   |  |                                  |  |  |  |
| With regard to the language, the in<br>language in which it was filed, unle  | and delicities and delicated dilicely  | uns nom.                         |  |  |  |
| the International search wa<br>Authority (Rule 23.1(b)).   | as carried out on the basis of a   | a translation of th              | e international appi                         | lication furnished to this                                 |  |
| b. With regard to any nucleotide and was carried out on the basis of the   |  |                                  | ernational applicati                         | on, the international search                               |  |
|  | nal application in written form.   |                                  |  |  |  |
| Tied together with the inten   | filed together with the international application in computer readable form.   |                                  |  |  |  |
| furnished subsequently to this Authority in written form.  |  |                                  |  |  |  |
| furnished subsequently to this Authority in computer readble form.   |  |                                  |  |  |  |
| the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished. |  |                                  |  |  |  |
| the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished                                  |  |                                  |  |  |  |
| Certain claims were found  | d unsearchable (See Box I).  |                                  |  |  |  |
| Unity of invention is lacking  |  |                                  |  |  |  |
| . With regard to the title,  |  |                                  |  |  |  |
| the text is approved as subn   | nitted by the applicant.   |                                  |  |  |  |
| the text has been establishe   | d by this Authority to read as   | foliows:                         |  |  |  |
| OIL FROM I(MOMORDICA CH  | ARANTIA L.,) ITS   | METHOD OF                        | PREPARATION                                  | AND USES   |  |
| . With regard to the abstract,   |  |                                  |  |  |  |
|  | office of the state of the stat |                                  |  |  |  |
| the text is approved as subm<br>the text has been established<br>within one month from the da  | itted by the applicant.<br>d, according to Rule 38.2(b), to<br>the of mailing of this internation  | by this Authority a              | xoB it appears in Box                        | III. The applicant may,                                    |  |
|  |  | •                                | ,  | and Additionty.  |  |
| The figure of the drawings to be published   | ed with the abstract is Floure   | No.                              |  |  |  |
| The figure of the drawings to be published as suggested by the applican  | ed with the abstract is Figure   | No.                              | <u> </u>                                     | None of the flavore  |  |
| The figure of the drawings to be published   | ed with the abstract is Figure nt.   | No.                              | X  | None of the figures.                                       |  |



| Box'l     | Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)  |
|-----------|--|
| This inte | emational Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:  |
| 1. X      | Claims Nos.: 15 because they relate to subject matter not required to be searched by this Authority, namely:   |
|           | see FURTHER INFORMATION sheet PCT/ISA/210  |
| 2 🗌       | Claims Nos.: because they relate to parts of the international Application that do not comply with the prescribed requirements to such an extent that no meaningful international Search can be carried out, specifically: |
| з. 🗌      | Claims Nos.:<br>because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).  |
| Box II    | Observations where unity of invention is lacking (Continuation of item 2 of first sheet)   |
| inis inte | emational Searching Authority found multiple inventions in this international application, as follows:   |
| 1.        | As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.   |
| 2.        | As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.   |
| a 🔲       | As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:                       |
| 4.        | No required additional search fees were timely paid by the applicant. Consequently, this international Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:           |
| Remark    | The additional search fees were accompanied by the applicant's protest.  No protest accompanied the payment of additional search fees.   |
|           |  |

International Application No. PCT/IN 99 00030

#### FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Although claim 15 is directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

Continuation of Box I.1

Claims Nos.: 15

Rule 39.1(iv) PCT — Method for treatment of the human or animal body by therapy

International Application No PCT/IN 99/00030

A. CLASSIFICATION OF SUBJECT TER

According to International Patent Classification (IPC) or to both national classification and IPC

#### B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols) IPC 7-A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

| C. DOCUM   | C. DOCUMENTS CONSIDERED TO BE RELEVANT   |                       |  |  |
|------------|--|-----------------------|--|--|
| Category * | Citation of document, with indication, where appropriate, of the relevant passages   | Relevant to claim No. |  |  |
| X          | ROSANE ARMOUGOM ET AL.: "COMPOSITION EN ACIDES GRAS DES EXTRAITS LIPIDIQUES DE QUELQUES GRAINES DE CUCURBITACEES TROPICALES."  O.C.L. OLEAGINEUX CORPS GRAS LIPIDES., vol. 5, no. 4, July 1998 (1998-07)  - August 1998 (1998-08), pages 323-328, XP000891603  EDITIONS JOHN LIBBEY EUROTEXT, MONTROUGE., FR  ISSN: 1258-8210 the whole document  -/ | 1,2,9-12              |  |  |

| Further documents are listed in the continuation of box C.  | Patent family members are listed in annex.  |  |
|---|---|--|
| "Special categories of cited documents:  "A" document defining the general state of the art which is not considered to be of particular relevance  "E" earlier document but published on or after the international filling date  "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)  "O" document referring to an oral disclosure, use, exhibition or other means  "P" document published prior to the international filing date but later than the priority date claimed | "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention.  "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone.  "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person sidiled in the art.  "&" document member of the same patent family |  |
| Date of the actual completion of the international search   | Date of mailing of the International search report  |  |
| 3 April 2000  | 10/04/2000  |  |
| Name and mailing address of the ISA   | Authorized officer  |  |
| European Patent Office, P.B. 5816 Patentiaan 2<br>NL – 2280 HV Rijswijk<br>Tel. (+31–70) 340–2040, Tx. 31 651 epo ni,<br>Fax: (+31–70) 340–3016   | Rempp, G  |  |

1

International Application No
PCT/IN 99/00030

| C.(Continuation) DOCUMENTS CONDERED TO BE RELEVANT |  |                       |  |  |
|--|--|-----------------------|--|--|
| Category °   | Citation of document, with indication, where appropriate, of the relevant passages   | Relevant to claim No. |  |  |
| X .  | S. P. TANDON ET AL.: "STUDY OF CUCUMIS MELO MOMORDICA SEED OIL." JOURNAL OF THE INDIAN CHEMICAL SOCIETY., vol. 53, no. 11, November 1976 (1976-11), pages 1161-1162, XP000901224 THE INDIAN CHEMICAL SOCIETY, CALCUTTA., IN ISSN: 0019-4522 the whole document | 1,9-12                |  |  |
| A  | US 5 916 573 A (CLEAVES FREDERICK T ET AL) 29 June 1999 (1999-06-29) cited in the application  |                       |  |  |
| A  | US 5 900 240 A (GLOMSKI PETER ET AL) 4 May 1999 (1999-05-04) cited in the application  |                       |  |  |
|  |  |                       |  |  |
|  |  |                       |  |  |
|  |  |                       |  |  |
|  |  |                       |  |  |
|  |  |                       |  |  |
|  |  |                       |  |  |
|  |  |                       |  |  |
| _  |  |                       |  |  |

Information on patent family members

International Application No PCT/IN 99/00030

| Patent document<br>cited in search report |   | Publication date | Patent farmy<br>member(s) | Publication date |
|---|---|------------------|---------------------------|------------------|
| US 5916573                                | Α | 29-06-1999       | NONE                      |                  |
| US 5900240                                | A | 04-05-1999       | NONE                      |                  |

# (19) World Intellectual Property Organization International Bureau





(43) International Publication Date 25 January 2001 (25.01.2001)

**PCT** 

# (10) International Publication Number WO 01/05416 A1

(51) International Patent Classification7: A61K 35/78

(21) International Application Number: PCT/IN99/00030

(22) International Filing Date: 15 July 1999 (15.07.1999)

(25) Filing Language: English

(26) Publication Language: English

(71) Applicant and

(72) Inventor: KHANNA, Pushpa [IN/IN]; E14/7 1st floor, Vasant Vihar, New Delhi 110 057 (IN).

(74) Agent: GABRIEL, Devadoss, Caleb; Kumaran & Sagar, 84-C, C-6 Lane, (Off Central Avenue), Sainik Farms, New Delhi 110 062 (IN).

(81) Designated States (national): AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE,

ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

#### Published:

- With international search report.
- With amended claims and statement.

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

1/05416 AI

(54) Title: OIL FROM MOMORDICA CHARANTIA L., ITS METHOD OF PREPARATION AND USES

(57) Abstract: The present invention relates to a novel oil extracted from the seeds of *Momordica charantia L.*, for topical application to a body of mammal and used as anti-inflammatory, anti-arthritic, vasculodilatory and wound healing agent, said oil essentially comprising capric acid 0.7-1.2 % by wt., lauric acid 0.6-1 % by wt., palmitic acid 4.2-5.0 % by wt., stearic acid 59-62 % by wt., oleic acid 13-15 % by wt., archid acid 3-5 % by wt., linoleic acid 8-10 % by wt., and other undetected minor acids 6-8 % by wt.; and a process for producing such oil.

→ 3/PRTS

10/031288 531 Rec'd PCT/F: 14 JAN 2002

# OIL FROM I(MOMORDICA CHARANTIA L.,) ITS METHOD OF PREPARATION AND USES

#### Field of the invention

The invention relates in general, to a novel oil extracted from the seeds of

Momordica charantia L., (bitter gourd), its preparation and use as antiinflammatory, anti-arthritic, vasculodilatory and wound healing agent.

### Background

15

20

25

30

The invention relates to a novel oil extracted from the seeds of *Momordica charantia L.*, (bitter gourd). *Momordica charantia* is a perennial herb of the family Cucurbitaceae, widely grown in Asia. The herb is endemic to tropical countries like India, S. Africa, Philippines, China and Burma. The species of *Momordica* found in western countries are different from the tropical species in that, the plants differ in morphological and organoleptic properties. Various parts of this plant, especially the fruits, have been widely used for preparation of hypoglycemic pharmaceutical compositions.

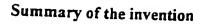
The extract/juice of the fruit is known to exhibit hypoglycemic properties and often recommended to reduce the blood sugar levels in patients suffering from diabetes mellitus.

## Description of related Prior Art

Natural oils from various plant sources have been used in variety of applications. For instance, US Patent 5,916, 573 discloses grapeseed oil for tropical application on the skin. Similarly, US Patent 5,900,240 discloses herbal compositions and their use as hypoglycemic agents. The composition of this

5

10



In accordance with the above and other objectives, the invention provides an oil composition prepared from the oil extracted from the seeds of *Momordica charantia L.*, essentially comprising a mixture of Capric acid, Lauric acid, Palmitic acid, Stearic acid, Oleic acid, Archidic acid, Linoleic acid, other undetected minor acids and esters.

The invention also provides a process for the extraction of oil from the seeds of Momordica charantia L., using non-polar solvents.

Further, the invention teaches the use of the oily composition in the treatment of arthritis, diabetes and other conditions developed in diabetic patients.

# Detailed description of the invention

15 Accordingly, the invention provides oil extracted from the seeds of *Momordica* charantia L., essentially comprising:

|    | 1.         | Coming 11                    |          |
|----|------------|------------------------------|----------|
|    | 1.         | Capric acid                  | 0.7-1.2% |
|    | 2.         | Lauric acid                  | 0.6-1%   |
| 20 | 3.         | Palmitic acid                | 4.2-5.0% |
|    | 4.         | Stearic acid                 | 59-62%   |
|    | <b>5</b> . | Oleic acid                   | 13-15%   |
|    | 6.         | Archid acid                  | 3-5%     |
|    | 7.         | Linoleic acid                | 8-10%    |
| 25 | 8.         | Other undetected minor acids | 6-8%     |
|    |            |                              |          |

Further, the invention provides a method for the extraction of oil from the seeds of Momordica charantia L., comprising the steps of:

5

10

15

20

In accordance with the present invention, the oil obtained from the seeds of *Momordica charantia L.*. is thick reddish-orange in colour, having bitter taste. The oil extracted by the method described hereinabove is obtained in 98.5% purity. The oil is water immiscible. However, it is soluble in non-polar solvents like benzene, petroleum ether, ethyl ether, acetone and hexane.

The applicant through continued usage and after rigorous experimentation has found that the oil exhibits anti-inflammatory, anti-arthritic, vasulodilatory properties as it contains several unsaturated components like linoleic acid, oleic acid etc. which are known for their antioxidant and anti-inflammatory properties.

It is found that the oil extracted from Momordica charantia L., is very thick and it is preferably used with diluents. Preferably, the oil may be mixed with other essential or vegetable oils. The essential oils that may be mixed with the oil from Momordica charantia could be selected from coconut oil, sesame oil, sunflower oil, olive oil, palm oil, groundnut oil or any such food grade oil. Further, it is found that when such food grade oils are mixed with the oils of Momordica, the penetration of the oil mixture into the outermost layers of the skin is enhanced to a great extent. The Momordica oil composition of the invention is prepared by mixing the 75% of the oil of Momordica charantia L., with vegetable oils selected from coconut oil, sesame oil sunflower oil, palm oil, olive oil or groundnut oil.

Momordica charantia oil composition may be prepared by mixing the oil extracted from Momordica charantia L., with vegetable oils and essential oils. The composition may also include, if desired, a botanical fragrance oil such as lavender oil, sandalwood oil and geranium oils. The oil composition may further include a perfume component or other pharmaceutically acceptable additives. The oil composition is generally in the form of oil, cream, lotion, gel, capsule

Figure 4 represents the condition of the wound on the same patient one month after application of the oil composition of the invention.

Figure 5 represents the condition of the foot of the same patient two months after application of the oil composition of the invention.

The invention is described in detail with respect to the following examples which are provided as illustrative embodiments only. These examples should not be construed to limit the scope of the invention in any manner. Modifications and alterations of the invention that may be apparent to those in the art are deemed to be included within the scope of the invention.

# Example - 1. (Oil preparative example)

15

20

25

10

Extraction of oil from Momordica charantia L.:

100 gms of dry seeds were taken from the ripe fruits of Momordica charantia L.,. The seeds were split. The split seeds were then thoroughly washed with water 3-4 times to render them substantially free of all impurities. The seeds were then dried under vacuum and pulverized to a fine powder using a milling device.

Any other conventional device may also be used. The fine powder was then treated with acetone hexane solvent mixed in the ratio 1:2. The mixture was stirred thoroughly and allowed to stand for 48 hours at room temperature. The oil layer was separated. The oil that separates out as supernatant layer was collected. The oil was then treated with 2-5% zinc acetate dissolved in water so that the salts, last traces of proteins and other impurities are precipitated. The oil was centrifuged and analyzed on gas-liquid chromatograph. The oil purified using gas liquid chromatograph showed the presence of the following fatty acids:

5

25

The oil purified using gas liquid chromatograph showed the presence of the following fatty acids:

Capric acid 0.9%

Lauric acid 0.70%

Palmitic acid 4.8 %

Stearic acid 60.1%

Oleic acid 13.81%

Archidic acid 3.28% and

Linoleic acid 10.00%

10 Other minor undetected acids 6.11%.

The oil also contains esters and other undetected minor ingredients.

## Example 3: Preparation of oil composition

The oil extracted from Momordica charantia L., as discussed in preparative examples 1-2 was kept in a beaker. Pure sesame oil was added to it in the ratio 3:1. The mixture was stirred continuously and thoroughly for 4-10 hours. Thereafter, fragrance oil like sandalwood oil as well as a perfume component were added to the mixture and stirred continuously and thoroughly for 4-10 hours. The formulation thus prepared stored in a container in a cool dry place.

The oil composition of the present invention can be formulated in a wide variety physical forms which include solutions, lotions, creams, oils, gels, sticks, sprays, ointments, balms, pastes, aerosols etc.

For preparation of an ointment, the active ingredients of the oil composition can be incorporated in any pharmacologically acceptable carrier, which is suitable for topical administration to the human skin. As such, the pharmacologically

acceptable carrier must be of sufficient purity and have low toxicity to render it

suspensions, creams, etc.). The age group of these patients ranged from 30-80 The average duration of illness in the population was more than 5-6 years. All the patients prior to the treatment with the composition of the invention were using standard causes of therapy, exercise etc. Upon commencement with the oil composition as disclosed herein, the patients refrained from using other medications, except yoga and exercises. Specific excerpts from each case history is disclosed in the following examples.

## Example 4:

10

15

25

5

A 30 year old Female working as a Receptionist had a bruise at her right elbow The oil composition was applied to the bruise caused at the elbow. The elbow was first cleaned and dried and the oil composition was applied slowly using a cotton swab. The oil composition was regularly applied after every 4 hours, for about 3-5 weeks. At the end of 15 days, the bruise healed completely.

## Example 5:

The subject was a 65 year old male. This patient had a gangrenous wound on his right foot. The gangrene was in its advanced stages. It was a severe case of 20 gangrene affliction. As there was no fresh blood supply, no healing constituted veins. The oil formulation of the invention was applied by the patient for about 10-12 weeks topically. After each application, the patient reported relief from the pain he suffered. At the end of the 6th week itself, the wound started drying up and eventually after the 12 week the wound had healed completely. Figs 1 depicts the gangrenous wound at the time of commencement of the treatment using the oil formulation of the invention. Fig 2 shows the dried wound at the end of the 12th week of the treatment.

# Example 9:

A 35 year old male, Chartered Accountant suffered from osteoarthritis for more than 6 years. He complained of constant pain in the right knee and was unable to walk without a cane. His movements were restricted as the knee had become nearly stiff. Examination revealed that the synovial fluid had dried which lead to muscular tension. He had used oral drugs and pain killers, though of no avail.

This subject used the composition of the invention for about 3 months applying it continuously on the knee 3-4 times a day. After the first week the pain had reduced to a great extent. The subject was advised exercises to the extent possible. After 2 weeks, the patient could flex the knee to 45° with no pain. After 6 weeks, he could flex and rotate the knee in full range. He continued to apply the composition and after 8 weeks, was able to walk freely.

15

20

25

5

### Example 10:

In another case, a housewife aged 52 years suffered from obesity. In addition, the patient complained of pain in the knee and ankle due to inflammation. The patient could hardly walk. She was using standard medication comprising drugs and injections, which did not help her much.

When the patient started using the composition of the invention, (application on the knee & ankle 4 times a day) she experienced relief in the dumb constant pain in the first week itself. After 2-3 weeks, she could stand and start walking to a limited extent. At the end of the 3<sup>rd</sup> week, upward and downward movement at the ankle was possible. The knee was capable of flexing upto 45 degrees. After 8 weeks, the patient commenced regular walking, full movement/rotation of the knees and ankles.

The patient was advised to apply the oil composition of the invention about 4 times a day, coupled with regular exercise. The patient reported relief from pain after 2 weeks, she reported restoration of function of both hands.

5

### Example 14:

A manager aged 58 years, employed in a Bank, was suffering from diabetes mellitus. He also reported neuropathic symptoms with the rise in blood level. This patient was advised to apply the oil composition of the invention 4 times a day on his legs. He experienced relief and after 18 weeks reported complete relief from these symptoms.

#### Example 15:

15

20

10

A dog aged 3 years was wounded in a dog fight. The dog had a grievous wound on its left foreleg. The wound was about 1 cm in diameter and about ½ mm deep. The wound was cleaned and the oil composition of the invention was applied to it regularly after every 4 hours. After 10 days the wound started drying up giving rise to regeneration of tissues at the site of injury. After 30 days it was found that the wound had completely healed.

#### Example 16:

A horse aged 4 years was injured by a nail at the stable. The wound was 3 cm long and about ½ mm deep. This wound was cleaned thoroughly and the oil composition of the invention was applied to it nearly 3 – 4 times a day. After 10 days, sufficient amount of the tissue had grown over the wounded area and after 25 days, complete healing was observed.

## I CLAIM:

5

1. Novel oil extracted from the seeds of *Momordica charantia L.*, for topical application to a body of mammal and used as anti-inflammatory, anti-arthritic, vasculodilatory and wound healing agent, said oil essentially comprising:

|    | Capric acid                  | 0.7-1.2% by wt.  |
|----|------------------------------|------------------|
|    | Lauric acid                  | 0.6-1% by wt.    |
| 10 | Palmitic acid                | 4.2-5.0% by wt.  |
|    | Stearic acid                 | 59-62% by wt.    |
|    | Oleic acid                   | 13-15% by wt.    |
|    | Archid acid                  | 3-5% by wt.      |
|    | Linoleic acid                | 8-10% by wt. and |
| 15 | Other undetected minor acids | 6-8% by wt.      |

2. An oil as claimed in claim 1 wherein the preferred range of the ingredients of the oil is as under:-

Capric acid 0.9% by wt.

Lauric acid 0.8% by wt.

Palmitic acid 4.2 % by wt.

Stearic acid 60.90% by wt.

Oleic acid 13.30% by wt.

Archidic acid 3.20% by wt.

Linoleic acid 9.80% by wt. and

Other minor undetected components and acids 6.90% by wt.

(i)

- grinding dry seeds to a fine powder in a suitable mill, (ii) treating the pulverized seeds with a mixture of non-polar solvents,
- 5 (iii) allowing the mixture to stand for 48 hours at room temperature so that the oil separates out
  - (iv) collecting the oil from the supernatant layer using a separating funnel.
- 10 refluxing the mixture obtained in step (vi) with any non-polar (v) solvent to remove the last traces of oil, and
  - (vi) Purification of the oil by precipitating the salts with impurities in it.
- 15 10. A method as claimed in claim 9 wherein the seeds of Momordica charantia L., are split, washed thoroughly with water 2-3 times to render the seeds substantially free from impurities and dried under vacuum, before said grinding.
- 20 11. A method as claimed in claim 9 wherein the non-polar solvents used may comprise a mixture of acetone with an aromatic or aliphatic hydrocarbon selected from the group of benzene, hexane, petroleum ether and ethyl ether.
- 25 A method as claimed in claim 9 wherein the ratio of the aliphatic or 12. aromatic hydrocarbon in the non-polar solvent mixture may be 2:1.
  - 13. A method as claimed in claim 9 wherein 2-5% zinc acetate dissolved in water may be used to precipitate the proteins and other impurities in the oil.

### AMENDED CLAIMS

[received by the International Bureau on 08 2000 (08.06.00); Signal claims 1-15 replaced by new claims 1-12 (3 pages)]

1. Oil extracted from the seeds of *Momordica charantia L.*, useful as antiinflammatory, anti-arthritic, vasculodilatory and wound healing agent, said oil comprising essentially of::

Capric acid

10

15

.20

0.7-1.2% by wt.

Lauric acid

0.6-1% by wt.

Palmitic acid

4.2-5.0% by wt.

Stearic acid

59-62% by wt.

Oleic acid

13-15% by wt.

Archidic acid

3-5% by wt.

Linoleic acid

8-10% by wt.

Other undetected minor acids

6-8% by wt.

2. Oil as claimed in claim 1 wherein the preferred range of the ingredients of the oil is as under:-

Capric acid 0.9% by wt.

Lauric acid 0.8% by wt.

Palmitic acid 4.2 % by wt.

Stearic acid 60.90% by wt.

Oleic acid

13.30% by wt.

Archidic acid 3.20% by wt.

Linoleic acid 9.80% by wt.

Other fairfor undetected mixor acids 6.90% by wt.

25 3. A novel oil composition comprising:-

oil extracted from the seeds

70 to 80% by wt.

of Momordica charantia L,

one or more vegetable oils,

15 to 25% by wt.

5

10

15.

- (v) refluxing the mixture obtained in step (iv) with any non-polar solvent to remove the last traces of oil,
- (vi) purifying the oil by adding 2-5% zinc acetate dissolved in water to precipitate the salts with impurities from the oil, and
- (vii) analysis of the oil extracted by gas liquid chromatography.
- 9. A process as claimed in claim 8 wherein the seeds of *Momordica charantia*L., are split, washed thoroughly with water 2-3 times to render the seeds substantially free from impurities and dried under vacuum before said grinding.
- 10. A process as claimed in claim 8 wherein the non-polar solvent comprises a mixture of acetone with an aromatic or aliphatic hydrocarbon selected from the group of benzene, hexane, petroleum ether and ethyl ether.
- 11. A process as claimed in claim 10 wherein the ratio of the aliphatic or aromatic hydrocarbon in the non-polar solvent mixture is 2:1.
- 12. Use of an oil extracted from *Momordica charantia L* or its composition for treatment of inflammation, arthritis, vasculodilation and wounds in a patient body, by applying the oil or composition as claimed in claims 1 to 7 on the affected area of the patient body for a period of about six to twenty weeks.

### 2. Tandon et al:

This citation teaches extraction of oil from Cucumis melo momordica, which is a totally different plant. Whereas, the invention of the instant application relates to extraction of oil from Momordica charantia L. which is a different plant. Each species in Cucurbitaceae family provides oil having different constituents and properties. Therefore, the oils from the two different plants cannot be equated. The method of extraction used by Tandon et al. is the distillation method, whereas, a totally different method is taught by the invention of the application. The method taught by the citation involves the steps of heating by which unsaturated fatty acids are denatured (the double bonds in the unsaturated fatty acids is affected). The invention of the application teaches a method conducted at room temperature and pressure, whereby all the ingredients of the oil are extracted in their natural form and the oil thus extracted is pure and is capable of use for therapeutic purposes for mammals. The oil is extracted without affecting the efficacy of the oil.

## 3. US Patent 5,916,573:

This US Patent 5,916,573, has been referenced in the "prior art" section of the instant application and falls in "A" category. The patent teaches extraction of "grape seed oil" whereas the application relates to the extraction and use of oil from *Momordica charantia L*.

## 4. US Patent 5,900,240:

This US Patent 5,900,240 relates to a composition comprising several herbs one of which is *Momordica charantia* L. The composition is useful for treatment of hypoglycemic conditions in mammals. However, this citation does not disclose the oil and its use obtained from *Momordica charantia* L.

All the citations teach away from the invention of the application.

1/3 ...

10/031288

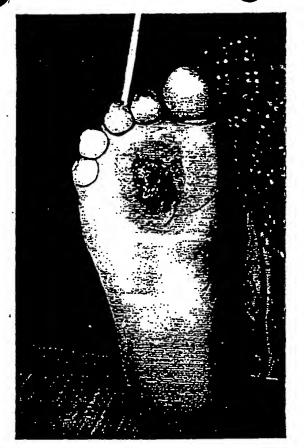


Figure 1



Figure 2

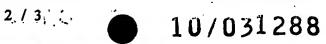




Figure 3



Figure 4

10/031288



Figure 5

PCT/IN 99/00030

|  |  | :  | PUI/IN 9   | 9/00030  |
|--|--|--|--|--|
| IPC 7  | A61K35/78  |  |  |  |
|  | to informational Patent Classification (IPC) or to both national class<br>SEARCHED   | efficiation and IPC  |  |  |
|  | ocumentation searched (classification system followed by classification system system followed by classification system syste | cetion eventois)   |  |  |
| IPC /  | A61K   |  |  |  |
|  | son searched other than minimum documentation to the extent th   |  |  |  |
| Sectionic d  | ata base consulted during the international search (name of data   | base and, where practical  | , eografi terme use  | <b>a)</b>  |
|  | ENTS CONSIDERED TO BE RELEVANT   |  |  |  |
| Category *   | Citation of document, with indication, where appropriate, of the   | relevant passages  |  | Relevant to claim No.  |
| <b>X</b>   | ROSANE ARMOUGOM ET AL.: "COMPOSACIDES GRAS DES EXTRAITS LIPIDIC QUELQUES GRAINES DE CUCURBITACES TROPICALES."  O.C.L. OLEAGINEUX CORPS GRAS LII vol. 5, no. 4, July 1998 (1998—6 — August 1998 (1998—08), pages XP000891603  EDITIONS JOHN LIBBEY EUROTEXT, PFR  ISSN: 1258—8210 the whole document  | QUES DE<br>ES<br>PIDES.,<br>07)<br>323-328,  |  | 1,2,9-12   |
|  | or documents are listed in the commussion of box C.  | X Patent family m  | embere are Seted i   | 1 GTHeX,   |
| "A" document consider do filtrig dat 1." document which is observed observed later than 100 document later document later than 100 document later docu | which may throw doubts on priority olstm(e) or crited to establish the publication date of emother or other especial research (see specified) trafeming to an onal deciceure, use, exhibition or same published prior to the international filling date but in the priority date claimed.  The priority date claimed transmissional seauch.  April 1 2000  | "I" later document publish or priority date and in clied to understand to triversition." "X" document of perfocular cernot be considered involve an investive or considered document to combine ments, such combine in the art.  "4" document member of Date of metting of the | of in conflict with if<br>the principle or the<br>relevence; the cle<br>d novel or carnot be<br>step when the doc.<br>I relevence; the cle<br>d to breake an inve-<br>d with one or more<br>fine being obvious<br>the earne patent to<br>the terme patent to | ne application but any underlying the intend invention to considered to the state alone the divention of the state alone the other such doou- to a person sidled milty |
| teme and mal   | Eng address of the IBA<br>European Patent Office, P.B. 6616 Patentiern 2<br>ML - 2200 HV Rightlift<br>Td. (431-70) 340-2040, Tz. 31 651 apo nl,<br>Fatt (461-70) 340-3016  | Authorized officer Resipp, G   |  |  |

1

| Bax i     | Observations where certain claims were found unsearchable (Continuation of firm 1 of first sheet)  |
|-----------|--|
| This inte | emissional Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:   |
| 1. X      | Claims Nos.: 15 because they relate to subject matter not required to be searched by this Authority, namely:   |
|           | see FURTHER INFORMATION sheet PCT/ISA/210  |
| 2 🗌       | Claims Nos.: because they reigh to parts of the international Application that do not comply with the precaibed requirements to such an extent that no meaningful international Search can be carried out, specifically: |
| 3. [      | Claims Nos.:<br>because they are dependent cisims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).  |
| Box #     | Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)   |
| This inte | imetional Searching Authority found multiple inversions in this international application, as follows:   |
|           |  |
|           |  |
| 1.        | As all required additional search fees were timely paid by the applicant, this intermational Search Report covers all searchable claims.   |
| 2 🗌       | As all searchable claims could be searched without effort justifying an additional tee, this Authority did not invite payment of any additional tee.   |
| 3. [      | As only some of the required additional search fees were timely paid by the applicant, this international Search Report covers only those claims for which fees were paid, specifically claims Nos.:                     |
|           |  |
| 4 🗌       | No required additional eserch fees were timely paid by the applicant, Consequently, this international Search Report is restricted to the invention first mentioned in the claims: it is covered by claims Nos.:         |
| Remark    | on Protest  The additional search fees were accompanied by the applicant's protest,  |
|           | No protest eccorroanied the payment of additional search less.   |

inversation on patent family members

PCT/IN 99/00030

| Patent document<br>clad in search report |   | Publication date | Patent family<br>member(s) | Publication date |
|--|---|------------------|----------------------------|------------------|
| US 5916573                               | A | 29-06-1999       | NONE                       |                  |
| US 5900240                               | A | 04-05-1999       | NONE                       |                  |

To:



DEVADOSS, Calab, Gabriel KUMARAN & SAGAR 84C, C6 Lane(Off Central Avenue) Sainik Farms 110 062 New Delhi

## PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing

(day/month/year)

24.10.2001

Applicant's or agent's file reference

IN/PA-98

INDE

IMPORTANT NOTIFICATION

International application No. PCT/IN99/00030

International filing date (day/month/year) 15/07/1999

Priority date (day/month/year)

15/07/1999

Applicant

KHANNA, Pushpa

- 1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
- 2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
- 3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

#### 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEAV

Authorized officer

- European Patent Office D-80298 Munich

10-60298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Ferro Vasconcelos, M

Fex: +49 89 2399 - 4465

Tel.+49 89 2399-7905





PCT (

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| Applicar                | it's or agent's file reference   | <del></del>  |   |
|-------------------------|--|--|---|
| IN/PA-                  | •  | FOR FURTHER ACTIO  | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)     |
|                         | onal application No.<br>199/00030  | International filing date (day/mill 15/07/1999   | onth/year) Priority date (day/month/year) 15/07/1999  |
| internation A61K3       | onal Patent Classification (IPC) or<br>5/78  | national classification and IPC  |   |
| Applicam<br>KHANN       | IA, Pushpa   |  |   |
| 1. This                 | international preliminary examinated in the applicant  | mination report has been prepa<br>t according to Article 36.   | red by this International Preliminary Examining Authority   |
| 2. This                 | REPORT consists of a total of  | of 6 sheets, including this cover  | sheet.  |
|                         | The second secon | ed by ANNEXES, i.e. sheets of<br>asks for this report and/or sheets<br>507 of the Administrative Instruc | the description, claims and/or drawings which have containing rectifications made before this Authority |
|                         | e annexes consist of a total o   |  | nono ander the POT).  |
| 3. This                 | report contains indications rela   | ating to the fallowing items:  |   |
| 1                       | Basis of the report  |  |   |
| 11                      | ☐ Priority   |  |   |
| III                     | Non-establishment of c   | pinion with regard to novelty, in  | ventive step and industrial applicability   |
| įV                      | LECK OF LINKY OF LINVENTIC   | on   |   |
|                         | Reasoned statement un<br>citations and explanation   | nder Article 35(2) with regard to<br>ons suporting such statement  | novelty, inventive stop or industrial applicability;  |
| VI                      | ☐ Certain documents cité   | <b>x</b> d   |   |
| VII                     | ☐ Certain defects in the in  | nternational application   |   |
| Vill .                  | ☐ Certain observations on  | the international application  |   |
| late of subi            | mission of the demand  | Date of  | completion of this report   |
| 5/10/200                | 90   | 24.10.20   | 001   |
| ame and n<br>wiminary   | nailing address of the international examining authority:  | Authorize  | ed officer  |
| 9)                      | European Patent Office<br>D-80298 Munich<br>Tel. +49 89 2399 • 0 Tx; 523656 (  | Markop   | oulos, E  |
| Fax: 449 89 2399 - 4465 |  |  | No. +49 89 2399 8658  |

Form PCT/IPEA/409 (cover sheet) (January 1994)

| 1. | Basis | of the | report |
|----|-------|--------|--------|
|----|-------|--------|--------|

| 1. | 1. With regard to the elements of the international application (Replacement sheets which have been furnish<br>the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally fi<br>and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)):<br>Description, pages: |  |                                       |                    |                      |                         |  |  |  |
|----|--|--|---------------------------------------|--------------------|----------------------|-------------------------|--|--|--|
|    | 1-3  | 3,6-16   | as originally filed                   |                    |                      |                         |  |  |  |
|    | 4,5  | i  | as received on                        | 02/08/2001         | with letter of       | 27/07/2001              |  |  |  |
|    | Cla  | nims, No.:   |                                       |                    |                      |                         |  |  |  |
|    | 1-1  | 2  | as received on                        | 02/08/2001         | with letter of       | 27/07/2001              |  |  |  |
|    | Dra  | awings, sheets:  |                                       |                    | •                    |                         |  |  |  |
|    | 1/3  | -3/3   | as originally filed                   |                    |                      |                         |  |  |  |
|    |  |  | . •                                   | :                  |                      | •                       |  |  |  |
| 2. | With regard to the <b>language</b> , all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.  These elements were available or furnished to this Authority in the following language: , which is:                            |  |                                       |                    |                      |                         |  |  |  |
|    |  |  |                                       |                    |                      |                         |  |  |  |
|    |  | the language of publication of the international application (under Rule 48.3(b)). |                                       |                    |                      |                         |  |  |  |
|    |  | the language of a 55.2 and/or 55.3).   | translation furnished for the         | purposes of interi | national preliminary | examination (under Rule |  |  |  |
| 3. | With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:   |  |                                       |                    |                      |                         |  |  |  |
|    |  | Contained in the international application in written form.                        |                                       |                    |                      |                         |  |  |  |
|    |  |  |                                       |                    |                      |                         |  |  |  |
|    |  |  |                                       |                    |                      |                         |  |  |  |
|    |  | ☐ furnished subsequently to this Authority in computer readable form.              |                                       |                    |                      |                         |  |  |  |
|    | The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.   |  |                                       |                    |                      |                         |  |  |  |
|    |  | The statement that listing has been ful  | t the information recorded in mished. | ocomputer readab   | le form is identical | to the written sequence |  |  |  |
| 4. | The  | amendments have  | resulted in the cancellation          | of:                |                      |                         |  |  |  |

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

|  |       | the description,  | pages:   |  |  |  |  |
|--|-------|---|--|--|--|--|--|
|  |       | the claims,   | Nos.:  |  |  |  |  |
|  |       | the drawings,   | sheets:  |  |  |  |  |
|  |       |   | :  |  |  |  |  |
| 5  | . 🛭   | This report has been considered to go bey   | established as if (some of) the amendments had not been made, since they have been rond the disclosure as filed (Rule 70.2(c)):  |  |  |  |  |
|  |       | (Any replacement sh<br>report.)<br>see separate sheet   | eet containing such amendments must be referred to under item 1 and annexed to this  |  |  |  |  |
| 6  | . Ad  | Additional observations, if necessary:  |  |  |  |  |  |
|  |       |   |  |  |  |  |  |
|  |       |   | inion with regard to novelty, inventive step and industrial applicability  |  |  |  |  |
| 1.   | . The | The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of: |  |  |  |  |  |
|  |       | the entire international  | application.   |  |  |  |  |
|  | Ø     | claims Nos. 12 in rega  | ard to industrial applicability.   |  |  |  |  |
| be   | caus  | se:   |  |  |  |  |  |
|  | Ø     | the said international and require an international see separate sheet  | national application, or the said claims Nos. 12 relate to the following subject matter which does in international preliminary examination (specify):   |  |  |  |  |
| the description, claims or drawings (indicate particular elements below) or said claims Nos. authat no meaningful opinion could be formed (specify): |       |   | or drawings (indicate particular elements below) or said claims Nos. are so unclear nion could be formed (specify):  |  |  |  |  |
|  |       | the claims, or said clai could be formed.   | ms Nos. are so inadequately supported by the description that no meaningful opinion  |  |  |  |  |
|  |       | no international search   | report has been established for the said claims Nos  |  |  |  |  |
|  | di C  | eaningful international p<br>or amino acid sequenc<br>uctions:  | preliminary examination cannot be carried out due to the failure of the nucleotide e listing to comply with the standard provided for in Annex C of the Administrative   |  |  |  |  |
|  |       | the written form has as   | t hoon franched as dealers and the second se |  |  |  |  |
|  |       |   | t been furnished or does not comply with the standard.   |  |  |  |  |
|  | _ '   |   | form has not been furnished or does not comply with the standard.  |  |  |  |  |

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

# INTERNATIONAL PRELIMINARY EXAMINATION RECEIPT

1. Statement

Novelty (N) Yes: Claims 1-12

No: Claims -

Inventive step (IS) Yes: Claims 1-12

No: Claims -

Industrial applicability (IA) Yes: Claims 1-11

No: Claims -

2. Citations and explanations see separate sheet

#### Re Item I

#### Basis of the opinion

The amendments filed with the letter dated July, 27th 2001 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT. The amendment concerned is the following: due to the probably accidential deletion of the word "seeds" in claim 3, oil from any part of the plant M. charantia would be included in the subject-matter of the claim.

#### Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claim 12 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

#### Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: ROSANE ARMOUGOM ET AL.: 'COMPOSITION EN ACIDES GRAS DES EXTRAITS LIPIDIQUES DE QUELQUES GRAINES DE CUCURBITACEES TROPICALES.' O.C.L. OLEAGINEUX CORPS GRAS LIPIDES., vol. 5, no. 4, July 1998 (1998-07) - August 1998 (1998-08), pages 323-328, XP000891603 EDITIONS JOHN LIBBEY EUROTEXT, MONTROUGE., FR ISSN: 1258-8210 D2: S. P. TANDON ET AL.: 'STUDY OF CUCUMIS MELO MOMORDICA SEED OIL.' JOURNAL OF THE INDIAN CHEMICAL SOCIETY., vol. 53, no. 11, November 1976 (1976-11), pages 1161-1162, XP000901224 THE INDIAN CHEMICAL SOCIETY, CALCUTTA., IN ISSN: 0019-4522

In accordance with the present invention, the oil obtained from the seeds of Momordica charantia L. is thick reddish-orange in colour, having bitter taste. The oil extracted by the method described hereinabove is obtained in 98.5% purity. The oil is water immiscible. However, it is soluble in non-polar solvents like benzene, petroleum ether, ethyl ether, acetone and hexane.

The applicant through continued usage and after rigorous experimentation has found that the oil exhibits anti-inflammatory, anti-arthritic, vasulodilatory properties as it contains several unsaturated components like linoleic acid, oleic acid etc which are known for their antioxidant & anti-inflammatory properties.

It is found that the oil extracted from Momordica charantia L, is very thick and it is preferably used with diluents. Preferably, the oil may be mixed with other essential or vegetable oils. The essential oils that may be mixed with the oil from Momordica charantia could be selected from coconut oil, sesame oil, sunflower oil, olive oil, palm oil, groundnut oil or any such food grade oil. Further, it is found that when such food grade oils are mixed with the oils of Momordica, the penetration of the oil mixture into the outermost layers of the skin is enhanced to a great extent. The Momordica oil composition of the invention is prepared by mixing the 75% of the oil of Momordica charantia L, with vegetable oils selected from coconut oil, sesame oil sunflower oil, palm oil, olive oil or groundnut oil.

Momordica charantia oil composition may be prepared by mixing the oil extracted from Momordica charantia L., with vegetable oils and essential oils. The composition may also include, if desired, a botanical fragrance oil such as lavender oil, sandalwood oil, rose oil and geranium oils. The oil composition may further include a perfume component or other pharmaceutically acceptable additives. The oil composition is generally in the form of oil, cream, lotion, gel, capsule

SUBSTITUTE SHEET (ART 34)

GOOD AMENDED SHEET

10

15

20

25

082605

25

35

531 Rec'4 PCT/PTC 14 JAN 2002

- (i) grin the dry seeds to a fine powder in a sure mill,
- (ii) treating the pulverized seeds with a mixture of non-polar solvents,
- 5 (iii) allowing the mixture to stand for 48 hours at room temperature so that the oil separates out,
  - (iv) collecting the oil from the supernatant layer using a separatory funnel,
- 10 (v) refluxing the mixture obtained in step (vi) with any non-polar solvent to remove the last traces of oil, and
  - (vi) purification of the oil by precipitating the salts with impurities in it,.
- In one embodiment, the seeds of *Momordica charantia L*, are split, washed thoroughly with water, 2-3 times to render it substantially free from impurities and dried under vacuum, before using the seeds for extraction of the oil.

In another embodiment, the non-polar solvents used for extraction of oil may comprise a mixture of acetone with an aromatic or aliphatic hydrocarbon selected from the group of benzene, hexane, petroleum ether and ethyl ether.

In yet another embodiment, the ratio of acetone to the aliphatic or aromatic hydrocarbon in the non-polar solvent mixture may be 2:1.

In yet another feature, 2-5% zinc acetate dissolved in water may be used to precipitate the proteins and other impurities in the oil.

In another feature, the oil extracted is analyzed for its fatty acid contents using gas liquid chromatography (GLC).

It may be noted that most of the plant parts of *Momordica* contain the oil disclosed by the invention, in varying degrees. As such, the oil may be extracted using any plant parts preferably seeds.

A novel oil composition comprising oil extracted from the seeds of Momordica charantia L 70 to 80% by wt., one or more vegetable oils-15 to 25% by wt., fragrance oil - 3% by wt, essential oil - 1% by wt, and at least one perfume component - 2% by wt.

SUBSTITUTE SHEET (ART 34)

CLAIMS:

Oil extracted from the seeds of Momordica charantia L., for topical application to the body of a mammal, useful as anti-inflammatory, anti-arthritic, vasculodilatory and wound healing agent, said oil comprising essentially of::

> Capric acid 0.7-1.28 by wt. Lauric acid 0.6-1% by wt. Palmitic acid 4.2-5.0% by wt. Stearic acid 59-62% by wt. Oleic acid 13-15% by wt. Arachidic acid 3-5% by wt. Linoleic acid 8-10% by wt. Other undetected minor acids 6-8% by wt.

Oil as claimed in claim 1 wherein the ingredients of the oil are as under:-

> Capric acid 0.9% by wt. Lauric acid 0.8% by wt. Palmitic acid 4:2 % by wt. Stearic acid 60.90% by wt. Oleic acid 13.30% by wt. Arachidic acid 3.20% by wt. Linoleic acid 9.80% by wt. Other minor undetected components and acids - 6.90% by wt.

A novel oil composition comprising:oil extracted from the 70 to 80% by wt. of Momordica charantia L. one or more vegetable oils, 15 to 25% by wt.

SUBSTITUTE SHEET (ART 34)

fragrance oil.
essential oil

3% by wt.

18 by wt.

and at least one perfume component 2% by wt.

- 4. An oil composition as claimed in claim 3 wherein the vegetable oil is selected from sesame oil, coconut oil, groundnut oil, olive oil, palm oil and other foodgrade oil.
- 5. An oil composition as claimed in claim 3 wherein the fragrance oil is selected from rose oil, sendalwood oil, geranium oil or lavender oil.
- 6. An oil composition as claimed in claim 3 wherein the composition is in physical forms selected from cream, gel, lotion, or combinations thereof.
- 7. An oil composition as claimed in claim 3 wherein the composition is prepared by mixing the oil extracted from Momordica charantia L. with suitable pharmaceutically acceptable carriers.
- 8. A process for the extraction of oil from the seeds of Momordica charactia L., comprising the steps of :
  - (i) grinding dry seeds to a fine powder in a suitable mill.
  - (ii) treating the pulverized seeds with a mixture of non- polar solvents,
  - (iii) allowing the mixture to stand for 48 hours at room temperature so that the oil separates out,
  - (iv) collecting the oil from the supernatant layer using a separating funnel,

SUBSTITUTE SHEET (ART 30)

- (v) refluxing the mixture obtained in step (iv) with any non-polar solvent to remove the last traces. of oil,
- (vi) purifying the oil by adding 2-5% zinc acetate dissolved in water to precipitate the salts with impurities from the oil, and
- (vii) analysis of the oil extracted by gas liquid chromatography.
- 9. A process as claimed in claim 8 wherein the seeds of Momordica charantia L., are split, washed thoroughly with water 2-3 times to render the seeds substantially free from impurities and dried under vacuum before the grinding in step (1).
- .10. A process as claimed in claim 8 wherein the non-polar solvent comprises a mixture of acetone with an aromatic or aliphatic hydrocarbon selected from the group of benzene, hexane, petroleum ether and ethyl ether.
- 11. A process as claimed in claim 10 wherein the ratio of the aliphatic or aromatic hydrocarbon in the non-polar solvent mixture is 2:1.
- 12. Use of the oil extracted from Momordica charantia L or its composition for treatment of inflammation, arthritis, vasculodilation and wounds in a patient body, by applying the oil or composition as claimed in claims 1 to 7 on the affected area of the patient body for a period of about six to twenty weeks.



REC'D 26 OCT 2001

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

|  | r ager  | nt's file reference  | FOR FURTHER ACTI  | See Notific ON Preliminary  | cation of Transmittal of International<br>y Examination Report (Form PCT/IPEA/416)       |
|--|---|--|---|---|--|
| IN/PA-98   |   |  | International filing date (day)   | /month/vear)  | Priority date (day/month/year)   |
| International  |   |  | 15/07/1999  | monary  | 15/07/1999   |
| PCT/IN99   |   |  |   |   |  |
| Internationa<br>A61K35/7                                 |   | nt Classification (IPC) or na  | ational classification and IPC  |   |  |
| Applicant  |   |  |   |   |  |
| KHANNA   | Pus   | hpa  |   |   |  |
|  |   |  |   | 1 to a dela dad   | ameticanal Proliminant Examining Authority   |
| 1. This in and is  | nterna<br>trans                                 | tional preliminary exam<br>mitted to the applicant   | nination report has been pro<br>according to Article 36.  | epared by this int  | ernational Preliminary Examining Authority   |
| 2. This F  | REPO  | RT consists of a total of  | f 6 sheets, including this co   | over sheet.   |  |
| h  |   | monded and are the ba  | ed by ANNEXES, i.e. sheet<br>sis for this report and/or sh<br>607 of the Administrative Ins   | eets containing i   | on, claims and/or drawings which have ectifications made before this Authority the PCT). |
| These  |   | exes consist of a total o  | 4 E abooto  |   |  |
| *******  | ann   | exes consist of a total o  | g 5 stieets.  |   |  |
|  | aime  | exes consist of a total o  | T 5 Streets.  |   |  |
| 3. This r  | eport   | contains indications rel   | ating to the following items  | :   |  |
| 3. This r  | eport   | contains indications rel   |   |   |  |
| 3. This r  | report  | contains indications rel  Basis of the report  Priority  | lating to the following items   |   | p and industrial applicability   |
| 3. This r<br>I<br>II                                     | eport   | contains indications rel<br>Basis of the report<br>Priority<br>Non-establishment of  | lating to the following items   |   | p and industrial applicability   |
| 3. This r  | eport   | contains indications rel<br>Basis of the report<br>Priority<br>Non-establishment of<br>Lack of unity of invent   | lating to the following items opinion with regard to nove tion under Article 35(2) with reg   | elty, inventive step<br>ard to novelty, in                                    | p and industrial applicability<br>ventive step or industrial applicability;              |
| 3. This r<br>I<br>II<br>III<br>IV<br>V                   | report  | contains indications rel<br>Basis of the report<br>Priority<br>Non-establishment of<br>Lack of unity of invent<br>Reasoned statement<br>citations and explanat   | lating to the following items opinion with regard to nove tion under Article 35(2) with reg tions suporting such statem   | elty, inventive step<br>ard to novelty, in                                    |  |
| 3. This r<br>II<br>III<br>IV<br>V                        | report  | contains indications rel<br>Basis of the report<br>Priority<br>Non-establishment of<br>Lack of unity of invent<br>Reasoned statement<br>citations and explanat<br>Certain documents c  | lating to the following items opinion with regard to nove tion under Article 35(2) with reg tions suporting such statem ited  | elty, inventive step<br>ard to novelty, in                                    |  |
| 3. This r  | report  | contains indications rel<br>Basis of the report<br>Priority<br>Non-establishment of<br>Lack of unity of invent<br>Reasoned statement<br>citations and explanat<br>Certain documents of<br>Certain defects in the                         | lating to the following items opinion with regard to nove tion under Article 35(2) with reg tions suporting such statem   | elty, inventive step<br>ard to novelty, invent                                |  |
| 3. This r II III IV V VI VII                             | report  | contains indications rel<br>Basis of the report<br>Priority<br>Non-establishment of<br>Lack of unity of invent<br>Reasoned statement<br>citations and explanat<br>Certain documents of<br>Certain defects in the                         | lating to the following items opinion with regard to nove tion under Article 35(2) with reg tions suporting such statem ited international application                              | elty, inventive step<br>ard to novelty, invent                                |  |
| 3. This r  II  III  IV  V  VI  VIII                      | eport   | contains indications rel<br>Basis of the report<br>Priority<br>Non-establishment of<br>Lack of unity of invent<br>Reasoned statement<br>citations and explanat<br>Certain documents of<br>Certain defects in the                         | lating to the following items opinion with regard to nove tion under Article 35(2) with reg tions suporting such statem ited international application on the international applica | elty, inventive step<br>ard to novelty, invent                                | ventive step or industrial applicability;  |
| 3. This r  II  III  IV  V  VI  VIII                      | report  | contains indications rel<br>Basis of the report<br>Priority<br>Non-establishment of<br>Lack of unity of invent<br>Reasoned statement<br>citations and explanal<br>Certain documents of<br>Certain defects in the<br>Certain observations | lating to the following items opinion with regard to nove tion under Article 35(2) with reg tions suporting such statem ited international application on the international applica | elty, inventive step<br>ard to novelty, invent                                | ventive step or industrial applicability;  |
| 3. This r II III IV V VI VII VIII  Date of sull 25/10/20 | report  S S S D D D D D D Mailin                | contains indications reliberations of the report Priority Non-establishment of Lack of unity of invent Reasoned statement citations and explanat Certain documents of Certain defects in the Certain observations on of the demand       | lating to the following items opinion with regard to nove tion under Article 35(2) with reg tions suporting such statem ited international application on the international applica | ard to novelty, invention  Date of completion                                 | ventive step or industrial applicability;  |
| 3. This r IIIIIV V VI VIII Date of sul                   | report  | contains indications reliberations for the report Priority Non-establishment of Lack of unity of invent Reasoned statement citations and explanat Certain documents of Certain defects in the Certain observations on of the demand      | opinion with regard to nove<br>tion<br>under Article 35(2) with reg<br>tions suporting such statem<br>ited<br>international application<br>on the international applica             | ard to novelty, invention  Date of completion  24.10.2001  Authorized officer | ventive step or industrial applicability;  of this report                                |
| 3. This r II III IV V VI VII VIII  Date of sull 25/10/20 | eport  eport  mailing mailing y exam y exam D-8 | contains indications reliberations for the report Priority Non-establishment of Lack of unity of invent Reasoned statement citations and explanat Certain documents of Certain defects in the Certain observations on of the demand      | opinion with regard to nove<br>tion<br>under Article 35(2) with reg<br>tions suporting such statem<br>ited<br>international application<br>on the international applica             | ard to novelty, invention  Date of completion                                 | ventive step or industrial applicability;  of this report                                |

| I. Basis | of the | report |
|----------|--------|--------|
|----------|--------|--------|

| I. | Basi   | asis of the report                                |   |                                      |  |   |  |  |
|----|--|---|---|--------------------------------------|--|---|--|--|
| 1. | With regard to the <b>elements</b> of the international application (Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)): Description, pages: |   |   |                                      |  |   |  |  |
|    | 1-3,6  | 6-16  | as originally filed   |                                      |  |   |  |  |
|    | 4,5  |   | as received on  | 02/08/2001                           | with letter of                             | 27/07/2001                                    |  |  |
|    | Clai   | ms, No.:  |   |                                      |  |   |  |  |
|    | 1-12   | 2   | as received on  | 02/08/2001                           | with letter of                             | 27/07/2001                                    |  |  |
|    | Drav   | wings, sheets:                                    |   |                                      |  |   |  |  |
|    | 1/3-   | 3/3   | as originally filed   |                                      |  |   |  |  |
|    |  |   |   |                                      |  |   |  |  |
| 2. | With<br>lang   | n regard to the l <b>an</b><br>Juage in which the | guage, all the elements mark<br>international application was | ed above were a<br>filed, unless oth | available or furnish<br>erwise indicated u | ned to this Authority in the under this item. |  |  |
|    | The  | se elements were                                  | available or furnished to this                                | Authority in the                     | following language                         | e: , which is:                                |  |  |
|    |  | the language of a                                 | translation furnished for the p                               | ourposes of the                      | international searc                        | ch (under Rule 23.1(b)).                      |  |  |
|    |  | the language of p                                 | publication of the international                              | application (und                     | der Rule 48.3(b)).                         |   |  |  |
|    |  | the language of a 55.2 and/or 55.3)               | $oldsymbol{	ext{translation furnished for the p}}.$           | ourposes of inte                     | rnational prelimina                        | ary examination (under Rule                   |  |  |
| 3  | . Witl<br>inte   | n regard to any <b>nu</b><br>rnational prelimina  | cleotide and/or amino acide<br>ary examination was carried o  | sequence disclout on the basis of    | osed in the interna<br>of the sequence lis | tional application, the sting:                |  |  |
|    |  | contained in the i                                | nternational application in wri                               | tten form.                           |  |   |  |  |
|    |  |   | n the international application                               |                                      | dable form.                                |   |  |  |
|    |  |   | quently to this Authority in writ                             |                                      |  |   |  |  |
|    |  | furnished subsec                                  | quently to this Authority in com                              | nputer readable                      | form.                                      |   |  |  |
|    |  | The statement the                                 | at the subsequently furnished application as filed has been t | l written sequen<br>furnished.       | ce listing does not                        |   |  |  |
|    |  | The statement the                                 | at the information recorded in                                | computer read                        | able form is identic                       | cal to the written sequence                   |  |  |
| 4  | . The  | e amendments hav                                  | ve resulted in the cancellation                               | of:                                  |  |   |  |  |



|      |      | the description,  | pages:   |
|------|------|---|--|
|      |      | the claims,   | Nos.:  |
|      |      | the drawings,   | sheets:  |
| 5.   | ×    | considered to go be   | n established as if (some of) the amendments had not been made, since they have been yond the disclosure as filed (Rule 70.2(c)):  |
|      |      | (Any replacement s report.) see separate shee                     | heet containing such amendments must be referred to under item 1 and annexed to this   |
| _    |      |   |  |
| 6.   | Add  | ditional observations,  | ii fiecessary.   |
|      |      |   |  |
| III. | No   | n-establishment of  | opinion with regard to novelty, inventive step and industrial applicability  |
| 1.   | The  | auestions whether t   | the claimed invention appears to be novel, to involve an inventive step (to be non-<br>irially applicable have not been examined in respect of:                                |
|      |      | the entire internatio   | nal application.   |
|      | ×    | claims Nos. 12 in re  | egard to industrial applicability.   |
| bo   | cau  | eo.   |  |
| DE   | cau  |   | to the following subject matter which does   |
|      | ×    | the said internation<br>not require an inter<br>see separate shee | al application, or the said claims Nos. 12 relate to the following subject matter which does<br>national preliminary examination ( <i>specify</i> ):<br>et                     |
|      |      | the description, cla<br>that no meaningful                        | ims or drawings (indicate particular elements below) or said claims Nos. are so unclear opinion could be formed (specify):   |
|      | 0    | the claims, or said could be formed.                              | claims Nos. are so inadequately supported by the description that no meaningful opinion  |
|      |      |   | arch report has been established for the said claims Nos   |
| 2    | an   | meaningful internatio<br>d/or amino acid sequ<br>structions:      | nal preliminary examination cannot be carried out due to the failure of the nucleotide lence listing to comply with the standard provided for in Annex C of the Administrative |
|      |      | the written form ha   | s not been furnished or does not comply with the standard.   |
|      |      | the computer read   | able form has not been furnished or does not comply with the standard.   |
|      | _    | <b>.</b>  |  |
| ٧    | . Re | easoned statement   | under Article 35(2) with regard to novelty, inventive step or industrial applicability;  |

citations and explanations supporting such statement





International application No. PCT/IN99/00030

1. Statement

Novelty (N) Yes: Claims 1-12

No: Claims -

Inventive step (IS) Yes: Claims 1-12

No: Claims -

Industrial applicability (IA) Yes: Claims 1-11

No: Claims -

2. Citations and explanations see separate sheet

#### Re Item I

#### Basis of the opinion

The amendments filed with the letter dated July, 27th 2001 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT. The amendment concerned is the following: due to the probably accidential deletion of the word "seeds" in claim 3, oil from any part of the plant M. charantia would be included in the subject-matter of the claim.

#### Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claim 12 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

#### Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: ROSANE ARMOUGOM ET AL.: 'COMPOSITION EN ACIDES GRAS DES EXTRAITS LIPIDIQUES DE QUELQUES GRAINES DE CUCURBITACES TROPICALES.' O.C.L. OLEAGINEUX CORPS GRAS LIPIDES., vol. 5, no. 4, July 1998 (1998-07) - August 1998 (1998-08), pages 323-328, XP000891603 EDITIONS JOHN LIBBEY EUROTEXT, MONTROUGE., FR ISSN: 1258-8210

D2: S. P. TANDON ET AL.: 'STUDY OF CUCUMIS MELO MOMORDICA SEED OIL.' JOURNAL OF THE INDIAN CHEMICAL SOCIETY., vol. 53, no. 11, November 1976 (1976-11), pages 1161-1162, XP000901224 THE INDIAN CHEMICAL SOCIETY, CALCUTTA., IN ISSN: 0019-4522

2. D1 describes fatty acid compositions of 6 cucurbitaceae seed oils such as M. charantia oil and compares them to each other. Since the amounts of the fatty acids listed (lauric, myristic, palmitic, palmitoleic, stearic, oleic, linoleic, linolenic, arachidic and gondoic acid) are different from claim 1 but for oleic acid (table 4), and since the extraction process involves heating and no standing for 48 hours at room temperature, moreover there is no purification as in step (vi), claims 1-12 can be regarded as novel in respect to D1.

D2 relates to the fatty acid content of a seed oil of a plant of the same family, Cucumis melo momordica, in relation with its cooling effect.

Hence, the subject-matter of claims 1-12 is novel (Article 33(2) PCT).

3. The problem to be solved by the present invention may be regarded as finding an alternative to the pharmaceutical preparations for topical administration exhibiting an antiinflammatory, vasculodilatory and anti-arthritic property.

The solution to this problem proposed in claims 1-12 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons: M. charantia is known as hypoglycemic agent, moreover it is used as anthelmintic, purgative, antiinfective agent and for diseases of the skin (D1: p. 324, col. 2, par. 1). The use of the oil extracted from the seeds for anti-inflammatory, vasculodilatory, woundhealing and anti-arthritic purpose cannot be derived from the prior art at hand.

4. For the assessment of the present claim 12 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

| From the: INTERNATIONAL PRELIM EXAMINING AUTHORITY |                      |          |  | ING AUTHORITY  |   |  |
|--|----------------------|----------|--|--|---|--|
| Ţ.   | То:                  |          |  |  |   | DOT                                      |
|  | DEVAD                | oss      | S, Calab, Gabriel  |  |   | PCT                                      |
|  | KUMAR                | IAN      | & SAGAR  | İ  |   |  |
|  |                      |          | ne(Off Central Avenue)   | [  |   | WRITTEN OPINION                          |
| - 1  | Sainik F<br>I 10 062 |          | ~  |  |   | William Per Grander                      |
| - 1  | NDE                  | . 130    | W Deilii   |  |   | (PCT Rule 66)                            |
|  |                      |          |  |  |   | ,  |
|  |                      |          |  |  | Date of mailing                               |  |
|  |                      |          |  | ,  | (day/month/year)                              | 10.07.2001                               |
| A  | pplicant's           | ora      | gent's file reference  |  | REPLY DUE                                     | within 1 month(s)                        |
|  | WPA-98               |          | gorita   |  | nere: 502                                     | from the above date of mailing           |
| In   | temation             | al app   | olication No.  | International filing date (d                             | lav/month/year)                               | Priority date (day/month/year)           |
| P  | CT/IN9               | 9/00     | 030  | 15/07/1999   | , , ,   | 15/07/1999                               |
| In   | temationa            | al Pai   | ent Classification (IPC) or bott                                   | h national classification and                            | IPC   |  |
| A  | 61K35/               | 78_      |  |  |   |  |
| AF   | plicant              |          |  |  | ·   | ***************************************  |
| K  | HANNA                | , Pu     | shpa   |  |   |  |
| 1.   | This w               | ·ritto   | a carining in the first draws                                      | L. M.'- I.A M.   |   |  |
| <b>'</b> ''  |                      |          | n opinion is the first drawn                                       |  |   | ing Authority.                           |
| 2.   | This o               | pinic    | on contains indications rela                                       | ting to the following iten                               | ns:   | •  |
|  | ı                    | Ø        | Basis of the opinion   |  |   |  |
|  | 11                   |          | Priority   |  |   |  |
|  | 111                  |          | Non-establishment of opi   | nion with regard to nove                                 | elty, inventive step ar                       | nd industrial applicability              |
|  | IV                   | <u>-</u> | Lack of unity of invention   |  |   | ,  |
|  | V                    | Ø        | citations and explanation  | er Rule 66.2(a)(ii) with r<br>s supporting such state    | regard to novelty, inv                        | entive step or industrial applicability; |
|  | VI                   | _        | Certain document cited   |  |   |  |
|  | . VII                | _        | Certain defects in the inte  |  |   |  |
|  | VIII                 | Β̈́З     | Certain observations on the  | he international applicat                                | ion   |  |
| 3.   | The ap               | plica    | nt is hereby invited to rep  | oly to this opinion.                                     |   |  |
|  | When?                |          | See the time limit indicated at request this Authority to grant    | pove. The applicant may, be<br>an extension, see Rule 66 | efore the expiration of the .2(d).            | nat time limit,                          |
|  | How?                 |          | By submitting a written reply, a For the form and the language     | accompanied, where appro<br>of the amendments, see F     | priate, by amendments<br>Rules 66.8 and 66.9. | . according to Rule 66.3.                |
|  | Also:                |          | For an additional opportunity to For the examiner's obligation to  | lo consider amendments ar                                | nd/or arguments, see Ai                       | ule 66.4 bis.                            |
|  |                      |          | For an informal communication                                      | n with the examiner, see Ru                              | ule 66.6.                                     | f  |
|  | If no rep            | ly is    | filed, the international prelimin                                  | lary examination report will                             | be established on the b                       | asis of this apinion.                    |
|  |                      |          | by which the international preli<br>sport must be established acco |  | 1/2001  |  |
|  | 3.40.11.11.10.1      |          | shorr mast na asignishad acco                                      | numy to Hule 69.2 is: 1 3/1                              | 172001  |  |
|  |                      |          |  |  |   |  |

Name and mailing address of the international preliminary examining authority:



Europaun Patent Office D-80298 Munich Tel =49 89 2399 - 0 Tx: 523656 apmij ij Fax. =49 89 2399 - 4465 Authorized officer / Examiner

Markopoulos, E

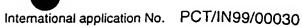
Egenalities officer ouch vetergiger of terre tents)

Exner, K

Felephone No. +49 89 2399 7826







#### I. Basis of the opinion

4.

|    |      |   | ments of the international application (Replacement sheets which have been furnished to response to an invitation under Article 14 are referred to in this opinion as "originally filed |
|----|------|---|---|
|    | 0    | escription, pages:                              |   |
|    | 1    | -16   | as originally filed   |
|    | ·    | laims, No.:                                     | ı   |
|    | 1.   | -12   | as amended under Article 19   |
|    | D    | rawings, sheets:                                | ·   |
|    | 1/   | 3-3/3   | as originally filed   |
|    |      |   |   |
| 2  | . Wi | ith regard to the lang<br>nguage in which the i | uage, all the elements marked above were available or furnished to this Authority in the ntemational application was filed, unless otherwise indicated under this item.                 |
|    | Th   | ese elements were a                             | vailable or furnished to this Authority in the following language: , which is:  |
|    |      | the language of a t                             | ranslation furnished for the purposes of the international search (under Rule 23.1(b)).   |
|    |      | the language of pu                              | blication of the international application (under Rule 48.3(b)).  |
|    |      | the language of a t 55.2 and/or 55.3).          | ranslation furnished for the purposes of international preliminary examination (under Rule  |
| 3. | Wit  | th regard to any nuclernational preliminary     | eotide and/or amino acid sequence disclosed in the international application, the examination was carried out on the basis of the sequence listing:                                     |
|    |      | contained in the inte                           | emational application in written form.  |
|    |      | filed together with the                         | ne international application in computer readable form.   |
|    |      | furnished subseque                              | ntly to this Authority in written form.   |
|    |      | furnished subseque                              | ntly to this Authority in computer readable form.   |
|    |      |   | the subsequently furnished written sequence listing does not go beyond the disclosure in<br>Dication as filed has been furnished.   |
|    |      | The statement that the listing has been furn    | the information recorded in computer readable form is identical to the written sequence iished.   |
| 4. | The  | amendments have r                               | esulted in the cancellation of:   |
|    |      | the description,                                | pages:  |
|    |      | the claims.                                     | Nos.:   |



|    | _     | _   |  |   |
|----|-------|-----|--|---|
|    |       | ١   | the drawings,  | sheets:   |
| 5  | 5. (2 | ₫   |  | established as if (some of) the amendments had not been made, since they have been and the disclosure as filed (Rule 70.2(c)):  |
|    |       |     | (Any replacement she<br>report.)<br>see separate sheet   | eet containing such amendments must be referred to under item 1 and annexed to this   |
| 6  | 5. A  | ddi | itional observations, if   | necessary:  |
| 11 | I. N  | on  | establishment of op  | inion with regard to novelty, inventive step and industrial applicability   |
| 1  |       | vio |  | claimed invention appears to be novel, to involve an inventive step (to be non-<br>ily applicable have not been and will not be examined in respect of:<br>application, |
|    | Ø     |     | claims Nos. 12 in rega   | rd to industrial applicability,   |
| b  | ecau  | ıse | <b>:</b> :   |   |
|    | Ø     | ſ   |  | pplication, or the said claims Nos. 12 relate to the following subject matter which does onal preliminary examination ( <i>specify</i> ):                               |
|    | 0     |     | •  | or drawings (indicate particular elements below) or said claims Nos. are so unclear nion could be formed (specify):   |
|    |       |     | he claims, or said clair<br>could be formed.   | ns Nos. are so inadequately supported by the description that no meaningful opinion   |
|    |       | n   | o international search   | report has been established for the said claims Nos   |
| 2. |       |     | The state of the s | drawn due to the failure of the nucleotide and/or amino acid sequence listing to ovided for in Annex C of the Administrative Instructions:                              |
|    |       | th  | ne written form has not  | been furnished or does not comply with the standard.  |
| i  |       | th  | ne computer readable :   | form has not been furnished or does not comply with the standard.   |
| ٧. |       |     |  | r Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; supporting such statement  |
|    |       | -   | nent<br>y (N)  | Claims  |
|    |       |     | ive step (IS)  | Claims  |



Industrial applicability (IA)

Claims .

2. Citations and explanations see separate sheet

#### VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made: see separate sheet

#### Re Item I

#### Basis of the opinion

The amendments filed with the International Bureau under Article 19(1) introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 19(2) PCT. The amendments concerned are the following: the deletion of the words "components and" in claim 2 since the percentage 6.90% refers to both undetected components and acids (see also page 10).

#### Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claim 12 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

#### Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- 1. Reference is made to the following documents:
  - D1: ROSANE ARMOUGOM ET AL.: 'COMPOSITION EN ACIDES GRAS DES EXTRAITS LIPIDIQUES DE QUELQUES GRAINES DE CUCURBITACEES TROPICALES.' O.C.L. OLEAGINEUX CORPS GRAS LIPIDES., vol. 5, no. 4, July 1998 (1998-07) August 1998 (1998-08), pages 323-328, XP000891603 EDITIONS JOHN LIBBEY EUROTEXT, MONTROUGE., FR ISSN: 1258-8210
  - D2: S. P. TANDON ET AL.: 'STUDY OF CUCUMIS MELO MOMORDICA SEED OIL.' JOURNAL OF THE INDIAN CHEMICAL SOCIETY., vol. 53, no. 11, November 1976 (1976-11), pages 1161-1162, XP000901224 THE INDIAN CHEMICAL SOCIETY, CALCUTTA., IN ISSN: 0019-4522

2. D1 describes fatty acid compositions of 6 cucurbitaceae seed oils such as M. charantia oil and compares them to each other. Since the amounts of the fatty acids listed (lauric, myristic, palmitic, palmitoleic, stearic, oleic, linoleic, linolenic, arachidic and gondoic acid) are different from claim 1 but for oleic acid (table 4), and since the extraction process involves heating and no standing for 48 hours at room temperature, moreover there is no purification as in step (vi), claims 1-12 can be regarded as novel in respect to D1.

D2 relates to the fatty acid content of a seed oil of a plant of the same family, Cucumis melo momordica, in relation with its cooling effect.

Hence, the subject-matter of claims 1-12 is novel (Article 33(2) PCT).

3. The problem to be solved by the present invention may be regarded as finding an alternative to the pharmaceutical preparations for topical administration exhibiting an anti-inflammatory, vasculodilatory and anti-arthritic property.

The solution to this problem proposed in claims 1-12 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons: M. charantia is known as hypoglycemic agent, moreover it is used as anthelmintic, purgative, antiinfective agent and for diseases of the skin (D1: p. 324, col. 2, par. 1). The use of the oil extracted from the seeds for anti-inflammatory, vasculodilatory, wound-healing and anti-arthritic purpose cannot be derived from the prior art at hand.

4. For the assessment of the present claim 12 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

#### Re Item VIII

### Certain observations on the international application

1. Claims 2, 3, and 5 are not supported by the description as required by Article 6 PCT, as their scope is broader than justified by the description and drawings. The reasons therefore are the following:

The range of the ingredients of claim 2 only is mentioned on page 10 as belonging to an oil composition and not as being the range of the oil.

Claim 3 is not supported in its entirety and "rose oil" in claim 5 is lacking in the description.

- 2. Furthermore, claim 5 is not clear in respect of "essential oil" since the mentioned oils are cited in the description as fragrance oils (p. 5).
- 3. The word "arachidic acid" is not correctly written.

## **PCT**

#### **DEMAND**

under Article 31 of the Patent Cooperation Treaty:

The undersigned requests that the international application specified below be the subject of International preliminary examination according to the Patent Cooperation Treaty and hereby elects all eligible States (except where otherwise indicated).

|   | For International Pro                                      | eliminary Examining Authorit                               | y use only                            | /   |
|---|--|--|---------------------------------------|---|
| Identification of IPEA  |  | Date of rece   | ipt of DE                             | MAND  |
| Box No.1 IDENTIFICATIO  | ON OF THE INTERNA  | TIONAL APPLICATION   | App                                   | licant's or agent's file reference            |
| International application No.  International filing date(day/month/year)  PCT/IN99/00030  July 15, 1999  (15.07.1999)  (Earliest)Priority date (day/month/year) |  |  | arliest)Priority date (day/month/year |   |
| Title of Invention:  "NOVEL OIL FROM MOM  Box No.II APPLICANT(S)  | ORDICA CHARANTI  | A-L, ITS METHOD OF PRI                                     | EPARAT                                | ION AND USES"                                 |
| Name and address: (Family name<br>The address m<br>KHANNA, Pushpa<br>E-14/7, 1st Floor<br>Vasant Vihar<br>New Delhi 110 057<br>India                            | followed by given name: for<br>ust include postal code and | r a legal entity, full official design<br>name of country) | action.                               | Telephone No.: 91-011-614-3619 Facsimile No.: |
| State (that is, country) of nationality   | y: IN  | State (that is, country) of r                              | esidence:                             | IN  |
| form PCT/IPEA/401(first sheet)(Ju   |  | <u> </u>   |                                       |   |

| C       | heet | - | b |
|---------|------|---|---|
| • • • • | иски | , | , |

International Application No.

| BOX NO.III AGENT OR COMMON PERPESENTATION OR APPROPRIE   | PC1/IN99/00030               |
|--|------------------------------|
| Box No.III AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRI  | ESPONDENCE                   |
| The following person is  X agent common representation and is hereby appointed and any earlier appointment of (an) agent(s)/common representation is hereby appointed, specifically for the procedure before the International Preliminar to the agent(s)/common representative appointed earlier. | ninary examination.          |
| Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country)  DEVADOSS CALAR CARREST  | Telephone No. (011) 653 3182 |
| DEVADOSS, CALAB, GABRIEL KUMARAN & SAGAR 84-C, C-6 Lane (Off Central Avenue) Sainik Farms New Delhi 110 062 INDIA.   | Facsimile No. (011) 653 3889 |
| Address for correspondence: Mark this check-box where no agent or common represer been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.   | ntative is/has               |
| orm PCT/IPEA/401 (second sheet)(July 1998; reprint July 1999)  |                              |

| International | Application | No |
|---------------|-------------|----|
| PCT/IN99/00   |             |    |

| Box !        | Box No.IV BASIS FOR INTERNATIONAL PRELIMINARY EXAMINATION |             |   |  |
|--------------|---|-------------|---|--|
| Staten<br>1. | ment concerning a<br>The applicant wi                     | mendme      | ents: * e international preliminary examination to start on the basis of:   |  |
|              | X the internati   | ional app   | plication as originally filed   |  |
| ı            | the description   | X           | as originally filed   |  |
|              |   |             | as amended under Article 34   |  |
|              | the claims  |             | as originally filed   |  |
|              |   | x           | as amended under Article 19 (together with any accompanying statement)  |  |
|              | •   |             | as amended under Article 34   |  |
|              |   |             | the drawings as originally filed  |  |
|              |   |             | as amended under Article 34   |  |
| 1            | The applicant wi  | shes any    | amendment to the claims under Article 19 to be considered as reversed.  |  |
| 2.           | amendments mad  | de under .  | start of the international preliminary examination to be postponed until the expiration of 20 date unless the International Preliminary Examining Authority receives a copy of any Article 19 or a notice from the applicant that he does not wish to make such amendments to box may be marked only where the time limit under Article 19 has not yet expired).  |  |
| <b>.</b>     | the International   | application | marked, international preliminary examination will start on the basis of the international iled or, where a copy of amendments to the claims under Article 19 and/or amendments of on under Article 34 are received by the International Preliminary Examining Authority up a written opinion or the international preliminary examination report, as so amended. |  |

Form PCT/IPEA/401 (third sheet)(July 1998; reprint July 1999)

|            | She  | ∞t No.4                                     | International Application No. PCT/IN99/00030               |
|------------|--|---|--|
| Lan        | guage for the purposes of internat   | ional preliminary examina                   | tion: English  |
| [2         |  |   |  |
|            | which is the language is a translat  | ion furnished for the purpos                | ses of international search.                               |
|            | which is the language of publicati   | on of the international appli               | cation.  |
|            | which is the language of the transpreliminary examination.                                   | lation (to be) furnished for the            | he purposes of international                               |
| Box        | No.V ELECTION OF STATES  |   |  |
| The a      | applicant hereby elects <u>all</u> eligible St   | ates (that is, all States which have        | been designated and which are bound by Chapte              |
|            | excluding the following States wh  | ich the applicant wishes not                | to elect :   |
| Box        | No.VI CHECK LIST   |   |  |
| Reterr     | emand is accompanied by the following elented to Box No.IV, for the purposes of internation: | ents, in the language<br>tional preliminary | For International Preliminary Examining Authority use only |
| I.         | translation of International application   | sheets                                      | received not received                                      |
| 2.         | amendments under Article 34  | sheets                                      |  |
| 3.         | copy (or, where required, translation) of amendment) under Article 19                        | sheets                                      |  |
| 4.         | copy (or, where required, translation) of amendment) under Article 19                        | sheets                                      |  |
| <b>5</b> . | letter   | 1 sheets                                    |  |
| 6.         | other (specify):   | sheets                                      |  |
| The den    | nand is also accompanied by the item(s) man  | ked below:                                  |  |
| 1. X       | fee calculation sheet  | 4. statement explaining la                  | ack of signature   |
| 2.         | separate signed power of attorney  | 5. nucleotide and or amin readable form     | o acid sequence listing in computer                        |
| 3.         | copy of general power of attorney, reference number, if any:                                 | 6. other (specify)                          |  |
| orm PC     | T/IPEA/401 (fourth sheet) (July 1998; reprint Jul  | y 1999)                                     |  |

| CL    |      |     |
|-------|------|-----|
| Sheet | INO. | . 2 |

International Application No.

| Sheet No.5   | PCT/IN99/00030  |
|--|---|
| Box No.VII SIGNATURE OF APPLICANT, AGENT OR (Next to each signature, indicate the name of the person signing and the capacity demand). | COMMON REPRESENTATIVE  of in which the person signs (if such capacity is not obvious from reading the  COLOL,  COLOL,  DEVADOSS, CALAB, GABRIEL |
| For International Preliminary  | Examining Authority use only  |
| 1. Date of actual receipt of DEMAND:   | Draining Authority use only   |
| 2. Adjusted date of receipt of demand due to CORRECTIONS under Rule 60.1(b):   |   |
| The date of receipt of the demand is AFTER the of 19 months from the priority date and item 4 does not apply.                          | e expiration or 5, below, The applicant has been informed accordingly.  |
| 4. The date of the demand is WITHIN the period of Rule 80.5  | 19 months from the priority date as extended by virtue of   |
| Although the date of receipt of the demand is after the delay in arrival is EXCUSED pursuant to Rul                                    | er the expiration of 19 months from the priority date, e 82.  |
|  |   |
| For International I  | Bureau use only   |
| Demand received from IPEA on :   | ·   |

|  | From th                     | e INTERNATIONAL B   | UREAU                                |
|--|-----------------------------|---|--------------------------------------|
| PCT  | To:                         | <u> </u>  |                                      |
| NOTIFICATION OF THE RECORDING OF A CHANGE  (PCT Rule 92bis.1 and Administrative Instructions, Section 422)  Date of mailing (day/month/year)   | Kum<br>84-C<br>(Off<br>Sain | RIEL, Devadoss, Caleb<br>aran & Sagar<br>, C-6 Lane<br>Central Avenue)<br>ik Farms<br>Delhi 110 062 | •                                    |
| 28 November 2000 (28.11.00)  | <u>  L</u>                  |   |                                      |
| Applicant's or agent's file reference IN/PA-98   |                             | IMPORTANT NOT   | IFICATION                            |
| International application No.  |                             | nal filing date (day/month/y  | ear)                                 |
| PCT/IN99/00030 ·   | 15 J                        | uly 1999 (15.07.99)   | <u> </u>                             |
| Name and Address   | X the agen                  | t the commo   | on representative State of Residence |
| GABRIEL, Devadoss, Caleb<br>Kumaran & Sagar  |                             | Telephone No.   |                                      |
| 16 Aradhana<br>R.K. Puram  | :                           | 91 011 688 5655   |                                      |
| Sector XIII<br>New Delhi 110 066   |                             | Facsimile No.   |                                      |
| India  |                             | 91 011 688 6070   |                                      |
|  |                             | Teleprinter No.   |                                      |
| 2. The International Bureau hereby notifies the applicant that t   | he following                | change has been recorded  | concerning:                          |
| the person the name X the add  | Iress                       | the nationality   | the residence                        |
| Name and Address   |                             | State of Nationality  | State of Residence                   |
| GABRIEL, Devadoss, Caleb<br>Kumaran & Sagar<br>84-C, C-6 Lane<br>(Off Central Avenue)  |                             | Telephone No.<br>91 011 653 3182  |                                      |
| Sainik Farms<br>New Delhi 110 062  |                             | Facsimile No.   |                                      |
| India  |                             | 91 011 653 3889   |                                      |
|  |                             | Teleprinter No.   |                                      |
| 3. Further observations, if necessary: The new agent's address on the Demand has be case of disagreement, the International Bureau   | en consid<br>should be      | ered as a change undo<br>notified immediately.  | er Rule 92bis. In                    |
| 4. A copy of this notification has been sent to:   |                             |   |                                      |
| X the receiving Office   | ſ                           | the designated Offices  | concerned                            |
| the International Searching Authority  | Ī                           | X the elected Offices cor   | ncerned                              |
| the International Preliminary Examining Authority  |                             | other:  | ·                                    |
| The later street of the street | Authorized                  | officer   |                                      |
| The International Bureau of WIPO 34, chemin des Colombettes  |                             | C. Cupello  |                                      |
| 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35   | Telephone                   | No.: (41-22) 338.83.38  |                                      |

| •  | From the INTERNATIONAL BUREAU   |
|--|---|
| PCT  | To:   |
| NOTIFICATION OF ELECTION   | Commissioner US Department of Commerce  |
| (PCT Rule 61.2)  | United States Patent and Trademark Office, PCT 2011 South Clark Place Room CP2/5C24 |
|  | Arlington, VA 22202 ETATS-UNIS D'AMERIQUE   |
| Date of mailing: 25 January 2001 (25.01.01)  | in its capacity as elected Office   |
| International application No.: PCT/IN99/00030  | Applicant's or agent's file reference: IN/PA-98                                     |
| International filing date:<br>15 July 1999 (15.07.99)  | Priority date:  |
| Applicant: KHANNA, Pushpa  |   |
| 1. The designated Office is hereby notified of its election made    X   in the demand filed with the International preliminary   25 October 206   in a notice effecting later election filed with the International preliminary   25 October 206 | r Examining Authority on: 00 (25.10.00)  national Bureau on:                        |

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland

Authorized officer:

Facsimile No.: (41-22) 740.14.35

J. Zahra Telephone No.: (41-22) 338.83.38



## INFORMATION CONCERNING ELECTED OFFICES NOTIFIED OF THEIR ELECTION

(PCT Rule 61.3)



To:

GABRIEL, Devadoss, Caleb Kumaran & Sagar 84-C, C-6 Lane (Off Central Avenue) Sainik Farms New Delhi 110 062 INDE

| Date of mailing (day/month/year)<br>25 January 2001 (25.01.01) |                         |                                       |                                |
|--|-------------------------|---------------------------------------|--------------------------------|
| Applicant's or agent's file reference IN/PA-98                 | -                       | IMPO                                  | DRTANT INFORMATION             |
| International application No.<br>PCT/IN99/00030                | International filing of | late (day/month/year)<br>9 (15.07.99) | Priority date (day/month/year) |
| Applicant KHANNA, Pushpa                                       |                         | ·                                     | · ·                            |

1. The applicant is hereby informed that the International Bureau has, according to Article 31(7), notified each of the following Offices of its election:

AP:GH,GM,KE,LS,MW,SD,SL,SZ,UG,ZW

EP:AT,BE,CH,CY,DE,DK,ES,FI,FR,GB,GR,IE,IT,LU,MC,NL,PT,SE

National: AU, BG, CA, CN, CZ, DE, IL, JP, KP, KR, MN, NO, NZ, PL, RO, RU, SE, SK, US

2. The following Offices have waived the requirement for the notification of their election; the notification will be sent to them by the International Bureau only upon their request:

EA: AM, AZ, BY, KG, KZ, MD, RU, TJ, TM

OA:BF,BJ,CF,CG,CI,CM,GA,GN,GW,ML,MR,NE,SN,TD,TG

National: AE,AL,AM,AT,AZ,BA,BB,BR,BY,CH,CU,DK,EE,ES,FI,GB,GD,GE,GH,GM,HR,

·HU,ID,IN,IS,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MD,MG,MK,MW,MX,PT,SD,SG,SI,SL,

TJ,TM,TR,TT,UA,UG,UZ,VN,YU,ZA,ZW

3. The applicant is reminded that he must enter the "national phase" before the expiration of 30 months from the priority date before each of the Offices listed above. This must be done by paying the national fee(s) and furnishing, if prescribed, a translation of the international application (Article 39(1)(a)), as well as, where applicable, by furnishing a translation of any annexes of the international preliminary examination report (Article 36(3)(b) and Rule 74.1).

Some offices have fixed time limits expiring later than the above-mentioned time limit. For detailed information about the applicable time limits and the acts to be performed upon entry into the national phase before a particular Office, see Volume II of the PCT Applicant's Guide.

The entry into the European regional phase is postponed until 31 months from the priority date for all States designated for the purposes of obtaining a European patent.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Authorized officer:

J. Zahra

Telephone No. (41-22) 338.83.38



## NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

From the II

NATIONAL BUREAU

To:

GABRIEL, Devadoss, Caleb Kumaran & Sagar 84-C, C-6 Lane (Off Central Avenue) Sainik Farms New Delhi 110 062 INDE

| IMPORTANT NOTICE |  |
|------------------|--|
|                  | /year)                                   |
|                  | day/month/year) Priority date (day/month |

 Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice: AU,KP,KR,US

In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:

AE,AL,AM,AP,AT,AZ,BA,BB,BG,BR,BY,CA,CH,CN,CU,CZ,DE,DK,EA,EE,EP,ES,FI,GB,GD,GE,GH,GM,HR,HU,ID,IL,IN,IS,JP,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MD,MG,MK,MN,MW,MX,NO,NZ,OA,PL,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,UA,UG,UZ,VN,YU,ZA,ZW
The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

 Enclosed with this Notice is a copy of the international application as published by the International Bureau on 25 January 2001 (25.01.01) under No. WO 01/05416

#### REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

#### REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Authorized officer

J. Zahra

Facsimile No. (41-22) 740,14,35

Telephone No. (41-22) 338.83 38

٠.,٠



July 27, 2001

European Patent Office D-80298 Munich, Germany

Attn: Mr. Markopoulos, E

Fax # 0049-89-2399-7826/4465

In Re: PCT/IN00/00030
Applicant: Khanna, Pushpa

International Filing Date: July 15, 1999

Priority date: July 15, 1999

Title: Novel oil from Momordica charantia L, its

method of preparation and uses

Our Ref: 001

Dear Sir,

We submit therewith our comments on the Written Opinion alongwith amendments to the claims and the description.

Since the Applicant is new to the PCT system, and in the event the Examiner has further queries, we may be given an opportunity, by way of an interview on a date convenient to the Examiner. Favourable consideration of the response is requested.

Yours faithfully,

D.C. GABRIEL

ATTORNEY FOR THE APPLICANT

KUMARAN & SAGAR

Encl: Response and amended claims

# IN THE INTERNATIONAL BUREAU OF WIPO 0 / 031288

In re International Application of: KHANNA, Pushpa

International Application No: PCT/IN99/00030

International filing date: July 15, 1999 (15.7.1999)

For: Novel oil from *Momordica charantia L*, its method of preparation and uses

#### RESPONSE TO THE WRITTEN OPINION

A written opinion drawn up by the International Preliminary Examining Authority was mailed on July 10, 2001. The response of the Applicant to the issues raised in the Written Opinion are as under:

#### 1. Amendment to the claims:

Claims 1 to 12 have been amended to make these claims clear and unambiguous. A marked up copy is attached to show the changes made in the claims. The amended claims have been drawn up on substitute sheets annexed herewith.

Claim 1: The word 'archidic' is corrected as 'arachidic'.

Further, in this claim, the words 'for topical application to the body of a mammal, and' has been inserted in this claim to restrict the scope of the claim to topical applications. This expression was present in the claims as originally filed and finds support in the specification as filed on pages 5, 6 at paragraphs 4, |lines 25 onwards. Further, specific support can be found on page 9, lines 26 to 30.

Claim 2: The words 'the preferred range of' before the word 'the ingredients' has been deleted to read as

'ingredients of the oil' only. The words 'components and' has been added after the word 'undetected'. The word 'minor' after 'detected' has been deleted. Support for the expression 'other minor undetected acids and components' can be found at page 8 line 10 of the specification. The word 'archidic' has been corrected as 'arachidic'.

Claim 3: Appearance of the word 'and' before 'oil' being erroneous has been deleted.

Claim 5: The word 'essential oil' has been replaced with the words 'fragrance oil'.

Claim 6: The word 'capsule' in this claim has been deleted as the composition is for topical administration only.

Claim 9: The words 'in step (i)' has been added after the word 'grinding' to make it clear that the grinding referred is that of step (i).

#### 2. Comments:

The Applicant requests consideration of the amended claims with the following comments:

- a. Re Item 1: The Examiner has expressed an opinion that deletion of the words 'components and' in the amendments made under Art 19, broadens the disclosure. Accordingly, the Applicant has now amended this claim to recite "Other minor undetected components and acids". This amendment is consistent with the disclosure as originally filed.
- b. Re Item VIII: Certain observations have been made as regards claims 2,3 and 5. These have been addressed as under:

- (i) Claim 2: The opening lines of this claim has been amended to read "Of as claimed in claim 1 wherein the ingredients of the oil are as under:-". This amendment restricts the scope of the claim to the ingredients of the oil only.
- (ii) Claim 3: It is mentioned that claim 3 is not supported in its entirety in the description. The Applicant submits that this claim does find support in the description. For example, paragraphs 3 and paragraph 4 bridging pages 5 and 6, describe the oil composition. Specifically, lines 20 to 29 at page 5 describe the oil composition. Similarly, example 3 on page 9 also describes the oil composition. As such, this claim is well supported by the description.

Yet, in order to remove all doubts and on the basis of the above support found in the description, the Applicant submits herewith pages 4 and 5 of the description wherein at lines 27 to 30, literal support for this claim has been inserted.

iii) Claim 5: Literal support for 'rose oil' appearing in claim 5 has now been provided at page 5 line............ of the description. The oils recited in this claim are indeed fragrance oils. And, therefore, the word 'essential oil' in claim 5 has been deleted.

4444 17-20

#### AMENDMENTS TO THE CLAIMS:

1. Oil exacted from the seeds of Momordica charantia

L., for topical application to the body of a mammal,

and useful as anti-inflammatory, anti-arthritic,

vasculodilatory and wound healing agent, said oil

comprising essentially of::

Capric acid 0.7-1.2% by wt.

Lauric acid 0.6-1% by wt.

Palmitic acid 4.2-5.0% by wt.

Stearic acid 59-62% by wt.

Oleic acid 13-15% by wt.

Arachidic acid 3-5% by wt.

Linoleic acid 8-10% by wt.

Other undetected minor acids 6-8% by wt.

2. Oil as claimed in claim 1 wherein the preferred range of the ingredients of the oil is are as under:-

Capric acid 0.9% by wt.

Lauric acid 0.8% by wt.

Palmitic acid 4.2 % by wt.

Stearic acid 60.90% by wt.

Oleic acid 13.30% by wt.

Arachidic acid 3.20% by wt.

Linoleic acid 9.80% by wt.

Other minor undetected  $\underline{\text{components}}$  and  $\underline{\text{minor}}$  acids 6.90% by wt.

3. A novel oil composition comprising:
and oil extracted from the 70 to 80% by wt.

of Momordica charantia L,

one or more vegetable oils. 15 to 25% by wt.

fragrance oil, essenti oil

3% by wt. 1% by wt.

and at least one perfume component 2% by wt.

- 4. An oil composition as claimed in claim 3 wherein the vegetable oil is selected from sesame oil, coconut oil, groundnut oil, olive oil, palm oil and other foodgrade oil.
- 5. An oil composition as claimed in claim 3 wherein the essential oil is selected from rose oil, sandalwood oil, geranium oil or lavender oil.
- 6. An oil composition as claimed in claim 3 wherein the composition is in physical forms selected from cream, gel, lotion, capsule or combinations thereof.
- 7. An oil composition as claimed in claim 3 wherein the composition is prepared by mixing the oil extracted from *Momordica charantia L*. with suitable pharmaceutically acceptable carriers.
- 8. A process for the extraction of oil from the seeds of *Momordica charantia L.*, comprising the steps of :
  - (i) grinding dry seeds to a fine powder in a suitable mill,
  - (ii) treating the pulverized seeds with a mixture of non-polar solvents,
  - (iii) allowing the mixture to stand for 48 hours at room.

    temperature so that the oil separates out,
  - (iv) collecting the oil from the supernatant layer using a separating funnel,

fragrance oil, essen oil

3% by wt.

1% by wt.

and at least one perfume component 2% by wt.

- 4. An oil composition as claimed in claim 3 wherein the vegetable oil is selected from sesame oil, coconut oil, groundnut oil, olive oil, palm oil and other foodgrade oil.
- 5. An oil composition as claimed in claim 3 wherein the essential fragrance oil is selected from rose oil, sandalwood oil, geranium oil or lavender oil.
- 6. An oil composition as claimed in claim 3 wherein the composition is in physical forms selected from cream, gel, lotion, capsule or combinations thereof.
- 7. An oil composition as claimed in claim 3 wherein the composition is prepared by mixing the oil extracted from *Momordica charantia L*. with suitable pharmaceutically acceptable carriers.
- 8. A process for the extraction of oil from the seeds of  $Momordica\ charantia\ L.$ , comprising the steps of :
  - (i) grinding dry seeds to a fine powder in a suitable mill,
  - (ii) treating the pulverized seeds with a mixture of non- polar solvents,
  - (iii) allowing the mixture to stand for 48 hours at room temperature so that the oil separates out.
  - (iv) collecting the oil from the supernatant layer using a separating funnel,

444 65-70

- (v) refluxing the mixture obtained in step (iv) with any non-polar solven to remove the last traces of oil,
- (vi) purifying the oil by adding 2-5% zinc acetate dissolved in water to precipitate the salts with impurities from the oil, and
- (vii) analysis of the oil extracted by gas liquid chromatography.
- 9. A process as claimed in claim 8 wherein the seeds of Momordica charantia L., are split, washed thoroughly with water 2-3 times to render the seeds substantially free from impurities and dried under vacuum before said—grinding\_in\_step (i).
- 10. A process as claimed in claim 8 wherein the non-polar solvent comprises a mixture of acetone with an aromatic or aliphatic hydrocarbon selected from the group of benzene, hexane, petroleum ether and ethyl ether.
- 11. A process as claimed in claim 10 wherein the ratio of the aliphatic or aromatic hydrocarbon in the non-polar solvent mixture is 2:1.
- 12. Use of the oil extracted from Momordica charantia L or its composition for treatment of inflammation, arthritis, vasculodilation and wounds in a patient body, by applying the oil or composition as claimed in claims 1 to 7 on the affected area of the patient body for a period of about six to twenty weeks.

#### CLAIMS:

1. Oil tracted from the seeds of Momordica charantia L., for topical application to the body of a mammal, and useful as anti-inflammatory, anti-arthritic, vasculodilatory and wound healing agent, said oil comprising essentially of::

Capric acid 0.7-1.2% by wt.

Lauric acid 0.6-1% by wt.

Palmitic acid 4.2-5.0% by wt.

Stearic acid 59-62% by wt.

Oleic acid 13-15% by wt.

Arachidic acid 3-5% by wt.

Linoleic acid 8-10% by wt.

Other undetected minor acids 6-8% by wt.

2. Oil as claimed in claim 1 wherein the ingredients of the oil are as under:-

Capric acid 0.9% by wt.

Lauric acid 0.8% by wt.

Palmitic acid 4.2% by wt.

Stearic acid 60.90% by wt.

Oleic acid 13.30% by wt.

Arachidic acid 3.20% by wt.

Linoleic acid 9.80% by wt.

Other minor undetected components and acids - 6.90% by wt.

3. A novel oil composition comprising:oil extracted from the 70 to 80% by wt.
of Momordica charantia L,
one or more vegetable oils, 15 to 25% by wt.

fragrance oil,
essertal oil
and at least one perfume component
2% by wt.

- 4. An oil composition as claimed in claim 3 wherein the vegetable oil is selected from sesame oil, coconut oil, groundnut oil, olive oil, palm oil and other foodgrade oil.
- 5. An oil composition as claimed in claim 3 wherein the fragrance oil is selected from rose oil, sandalwood oil, geranium oil or lavender oil.
- 6. An oil composition as claimed in claim 3 wherein the composition is in physical forms selected from cream, gel, lotion, or combinations thereof.
- 7. An oil composition as claimed in claim 3 wherein the composition is prepared by mixing the oil extracted from Momordica charantia L. with suitable pharmaceutically acceptable carriers.
- 8. A process for the extraction of oil from the seeds of *Momordica charantia L.*, comprising the steps of:
  - (i) grinding dry seeds to a fine powder in a suitable mill,
  - (ii) treating the pulverized seeds with a mixture of non- polar solvents,
  - (iii) allowing the mixture to stand for 48 hours at room temperature so that the oil separates out,
  - (iv) collecting the oil from the supernatant layer using a separating funnel.

- (v) refluxing the mixture obtained in step (iv) with non-polar solvent to recove the last traces of oil,
- (vi) purifying the oil by adding 2-5% zinc acetate dissolved in water to precipitate the salts with impurities from the oil, and
- (vii) analysis of the oil extracted by gas liquid chromatography.
- 9. A process as claimed in claim 8 wherein the seeds of Momordica charantia L., are split, washed thoroughly with water 2-3 times to render the seeds substantially free from impurities and dried under vacuum before the grinding in step (i).
- 10. A process as claimed in claim 8 wherein the non-polar solvent comprises a mixture of acetone with an aromatic or aliphatic hydrocarbon selected from the group of benzene, hexane, petroleum ether and ethyl ether.
- 11. A process as claimed in claim 10 wherein the ratio of the aliphatic or aromatic hydrocarbon in the non-polar solvent mixture is 2:1.
- 12. Use of the oil extracted from Momordica charantia L or its composition for treatment of inflammation, arthritis, vasculodilation and wounds in a patient body, by applying the oil or composition as claimed in claims 1 to 7 on the affected area of the patient body for a period of about six to twenty weeks.

- (i) grinding the dry seeds to a fine powder in a suita mill,
- (ii) treating the pulverized seeds with a mixture of non-polar solvents,
- 5 (iii) allowing the mixture to stand for 48 hours at room temperature so that the oil separates out,
  - (iv) collecting the oil from the supernatant layer using a separatory funnel,
- 10 (v) refluxing the mixture obtained in step (vi) with any non-polar solvent to remove the last traces of oil, and
  - (vi) purification of the oil by precipitating the salts with impurities in it,.
- In one embodiment, the seeds of *Momordica charantia L.*, are split, washed thoroughly with water, 2-3 times to render it substantially free from impurities and dried under vacuum, before using the seeds for extraction of the oil.
- In another embodiment, the non-polar solvents used for extraction of oil may comprise a
  20 mixture of acetone with an aromatic or aliphatic hydrocarbon selected from the group of
  benzene, hexane, petroleum ether and ethyl ether.

In yet another embodiment, the ratio of acetone to the aliphatic or aromatic hydrocarbon in the non-polar solvent mixture may be 2:1.

In yet another feature, 2-5% zinc acetate dissolved in water may be used to precipitate the proteins and other impurities in the oil.

In another feature, the oil extracted is analyzed for its fatty acid contents using gas liquid chromatography (GLC).

25

35

It may be noted that most of the plant parts of *Momordica* contain the oil disclosed by the invention, in varying degrees. As such, the oil may be extracted using any plant parts preferably seeds.

A novel oil composition comprising oil extracted from the seeds of *Momordica* charantia L 70 to 80% by wt., one or more vegetable oils-15 to 25% by wt., fragrance oil - 3% by wt. essential oil - 1% by wt, and at least one perfume component - 2% by wt.

In accordance with the present invention, the oil obtained from the seeds of *Momordica* charantia L., is thick reddish-orange in colour, having bitter taste. The oil extracted by the method described hereinabove is obtained in 98.5% purity. The oil is water immiscible. However, it is soluble in non-polar solvents like benzene, petroleum ether, ethyl ether, acetone and hexane.

5

10

15

2Ó

25

The applicant through continued usage and after rigorous experimentation has found that the oil exhibits anti-inflammatory, anti-arthritic, vasulodilatory properties as it contains several unsaturated components like linoleic acid, oleic acid etc which are known for their antioxidant & anti-inflammatory properties.

It is found that the oil extracted from *Momordica charantia L.*, is very thick and it is preferably used with diluents. Preferably, the oil may be mixed with other essential or vegetable oils. The essential oils that may be mixed with the oil from *Momordica charantia* could be selected from coconut oil, sesame oil, sunflower oil, olive oil, palm oil, groundnut oil or any such food grade oil. Further, it is found that when such food grade oils are mixed with the oils of *Momordica*, the penetration of the oil mixture into the outermost layers of the skin is enhanced to a great extent. The *Momordica* oil composition of the invention is prepared by mixing the 75% of the oil of *Momordica charantia L.*, with vegetable oils selected from coconut oil, sesame oil sunflower oil, palm oil, olive oil or groundnut oil.

Momordica charantia oil composition may be prepared by mixing the oil extracted from Momordica charantia L., with vegetable oils and essential oils. The composition may also include, if desired, a botanical fragrance oil such as lavender oil, sandalwood oil, rose oil and geranium oils. The oil composition may further include a perfume component or other pharmaceutically acceptable additives. The oil composition is generally in the form of oil, cream, lotion, gel, capsule